



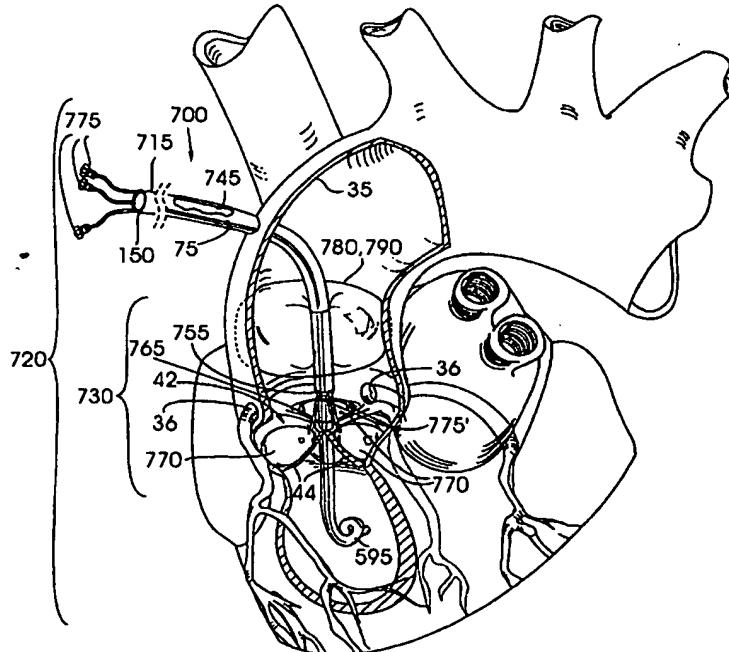
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 25/10, A61B 17/00		A1	(11) International Publication Number: WO 99/15223
			(43) International Publication Date: 1 April 1999 (01.04.99)
(21) International Application Number:	PCT/US98/20225	(81) Designated States:	AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date:	25 September 1998 (25.09.98)		
(30) Priority Data:	60/060,158 26 September 1997 (26.09.97) US		
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(54) Title: MULTI-FUNCTION AORTIC CATHETERIZATION AND BUMPER INSTRUMENT

(57) Abstract

An aortic catheterization and bumper instrument is formed with an elongated tubular shaft adapted to extend from an external location to a selected location in a patient's aortic root. The tubular shaft includes a lumen for communicating fluid from a proximal port to a distal port located within the aorta. The instrument incorporates a bumper device or mechanism with retractably deployable bumper elements configured to contact and engage the aortic root or aortic valve leaflets as the instrument is inserted into the patient's aorta to give tactile feedback to the surgeon that the instrument is precisely positioned in the intended location. Preferably, the bumper elements are shaped to conform to the shape of one or more leaflets of the aortic valve to hold the valve leaflets in a closed position when the bumper mechanism is deployed. Various configurations of the bumper elements are disclosed, including inflatable balloons, preshaped extendible wires and an extendible wire-frame skeleton that supports the bumper material. In addition, the instrument may also include a catheter position stabilizer-flow regulator, such as an inflatable aortic occlusion balloon which, when deployed, is designed to prevent flow of fluid past the stabilizer and to prevent longitudinal or radial displacement of the instrument when it is in the operative position.



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**MULTI-FUNCTION AORTIC CATHETERIZATION
AND BUMPER INSTRUMENT**

CROSS REFERENCES TO OTHER PATENT APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application serial number 60/060,158 filed on September 26, 1997 and U.S. Provisional Patent Application serial number 60/073,681 filed on February 4, 1998, the specifications of which are hereby incorporated by reference in their entirety.

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FIELD OF THE INVENTION

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The present invention relates generally to devices and methods for performing cardiovascular, cardiopulmonary and neurovascular surgical interventions which require the precise positioning of various types of percutaneously introduced surgical instruments into the vasculature of a patient using position signaling feedback from a bumper instrument, with or without the aid of imaging techniques such as transesophageal echocardiography, fluoroscopy, angioscopy, and others, and for restraining such instruments to resist movement once positioned within a lumen of the vasculature and to aid incompetent valves.

BACKGROUND OF THE INVENTION

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Interventions often require the percutaneous or cut-down introduction and precise placement of various types of catheter instruments and other surgical instruments, having elongated flexible shafts, within a lumen of the patient's vasculature close to a selected location where the intervention is to be performed. Such precise positioning has been previously accomplished in a number ways. In the typical procedure, a surgeon or other physician percutaneously introduces an internal distal end of the instrument through an incision in the patient's skin and into a peripheral blood vessel. The distal end is advanced a predetermined distance through the vessel to the selected location in either the peripheral vessel or in a central blood vessel upstream or downstream, or in a retrograde or antegrade direction, respectively,

from the point of introduction. The instrument is adapted to extend from the selected location to a location external to the patient. Such instruments are also introduced directly into the central blood vessels when peripheral access is not preferred or available or, for example, during either open chest procedures or minimally invasive, percutaneous procedures originating close to the central blood vessel.

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Once the distal end of the instrument has been advanced and positioned at the selected location, it is fixed into place longitudinally by various techniques. One technique is to engage and restrain an external segment of the elongated shaft of the instrument, thereby fixing the shaft in place relative to the insertion site. Although this technique is intended to maintain the distal end in a fixed longitudinal position, even if preshaped, it does not prevent the flexible shaft from being displaced within the blood vessel lumen and, for example, assuming an "S-shape" or serpentine disposition. Such a displacement will unavoidably change the location of the distal end and may require that the instrument be removed and repositioned.

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Past devices have attempted to overcome such displacement by incorporating symmetrical, inflatable volumetric balloons on the instrument shaft which, when inflated, will block fluid flow past the balloon and center the position of the distal end relative to the walls of the blood vessel lumen without distending the walls. However, while the balloon centers the distal end, the balloon itself is prone to wander longitudinally in the blood vessel lumen due to fluid pressure differentials which may exist, after inflation, on either the upstream or downstream side of the balloon. The longitudinal displacement of the balloon can result in either the instrument shaft or the exterior surface of the balloon becoming dislocated into a position which may block blood flow to the ostia of branch vessels. This type of displacement can have undesirable effects on a patient undergoing cardiopulmonary bypass because oxygenated blood flow to such branch vessels may be disrupted.

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Other monitoring techniques that have been developed to help guide a catheter device intralumenally include: ultrasound, fiber-optic, fluoroscopy, radiopaque markers and infrared sensing techniques. All of the above monitoring techniques are inefficient since they require monitoring equipment. The monitoring equipment occupies valuable operating room space, has

5 limited visualization, is prone to failure, and requires that either another individual be present to observe the visual display and communicate the instrument position to the surgeon or that the surgeon look away from the surgical field to observe the display. Furthermore, fluoroscopy requires the surgeon and other operating room personnel to wear lead aprons and other protective gear. This fluoroscopy protection is heavy, inconvenient, uncomfortable, and restrains the mobility and agility of the surgeon, in addition back injury can occur after prolonged use.

10 The surgeon must monitor the placement of the medical device as well as the secured position of the device in order to maintain a central position relative to the interior walls of the central or peripheral blood vessels in order to prevent the shaft from blocking the ostia of the vessels. In certain circumstances it is important to be able to maintain the central position for atraumatic introduction so as to minimize the potential for both injury to the vessel and dislodging of material, such as plaque, from the walls of the blood vessel. In contrast, it is also desirable in certain procedures to be able to maintain precise asymmetrical or non-centered positions for intentional dislodgment, dissolution and filtering of such material. This has been 15 accomplished in the past by using the above-described monitoring technique.

20 For surgical procedures involving cardioplegic arrest of the heart, the lumen of the ascending aorta proximate to the coronary arteries, between the aortic valve and the brachiocephalic trunk, is typically isolated from the aortic arch with either an inflatable, flow-regulating balloon flow control regulator disposed within the aortic lumen, or an externally applied aortic cross-clamp, positioned between the coronaries and the brachiocephalic trunk. During such a procedure, the patient undergoes full cardiopulmonary bypass with temperature controlled, oxygenated blood at a first temperature being perfused to the brain, visceral organs, arms and remainder of the body. At the same time, temperature controlled crystalloid 25 cardioplegia, or a mixture of blood and cardioplegia, at a second temperature is typically perfused to the isolated coronary arteries to maintain the heart in arrest. It is undesirable to perfuse cardioplegia to the brain and the rest of the body. Several problems can therefore arise if the inflatable balloon wanders in the lumen or if the cross-clamp is inadvertently dislodged.

5 If the balloon wanders upstream in a retrograde flow direction such that its exterior surface blocks the flow of temperature controlled blood and cardioplegia to the coronary arteries, occlusion of the coronaries would occur causing ischemia and/or necrosis of the myocardium. If the balloon wandered far enough upstream in the retrograde direction (e.g. across the aortic valve), oxygenated systemic blood would, in certain situations, flow into the coronaries causing spontaneous heartbeat to resume before the surgical procedure is completed. In the event the balloon wanders downstream in the antegrade flow direction past the brachiocephalic trunk, or if the external cross-clamp is dislodged, occlusion of the brachiocephalic trunk may occur causing cerebral ischemia and/or necrosis. Also, such wandering may cause cardioplegia to be perfused to the brain and the rest of the body instead of only into the heart arteries.

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15 The same problems exist where a fluid mixture of cardioplegia and/or blood is perfused to the coronary sinus in a retrograde direction through the coronary arterial bed and is aspirated from the aortic root as the fluid enters from the coronary ostia. Wandering of the balloon can also cause the instrument shaft to move from a central position in the blood vessel lumen to rest against the vessel walls blocking the ostia of branch vessels.

20 In the case of an incompetent regurgitant aortic valve or valve prosthesis, pressurized cardioplegia perfused to an isolated portion of the ascending aorta near the aortic valve will flow into the left ventricle instead of in an antegrade direction into the coronary arteries as is preferred. The same problem of cardioplegia entering the ventricle through an incompetent aortic valve may occur, in certain situations, with the retrograde cardioplegia perfusion procedure described above.

25 In patients with a healthy aortic heart valve or properly functioning valve prosthesis, the valve opens as blood is ejected from the left ventricle of the heart and into the aortic root. Once the left ventricle has fully contracted, blood flow past the aortic valve temporarily stops as the left ventricle begins to fill. Simultaneously, the leaflets of the normal aortic valve close together completely, under the back pressure from the blood in the aortic root downstream of the valve, preventing retrograde, upstream regurgitation of blood into the left ventricle from the ascending aorta. However, in incompetent aortic valves which are abnormal, calcified, damaged or otherwise unhealthy, the leaflets of the valve do not close completely together such that retrograde regurgitation of blood from the aortic root into the left ventricle occurs after each

contraction. Such retrograde regurgitation is undesirable especially in procedures in which the patient must be placed on cardiopulmonary bypass with the heart arrested and decompressed.

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Unexpected and/or uncontrolled transvalvular regurgitation of fluid into the left ventricle can seriously injure an arrested heart by causing, among other serious problems, abnormal distension of the heart due to excessive buildup of regurgitant fluid in the left ventricle or other chambers of the heart. Such unwanted regurgitation is also possible during typical cardiopulmonary bypass procedures where a transvalvular left ventricle vent has been introduced to aspirate the ventricle in situations where the vent has become clogged with embolic material, surgical debris or has otherwise ceased to function without warning.

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Accordingly, what has been needed and previously unavailable is a precision engineered aortic catheterization bumper instrument having an aortic bumper mechanism or device which is compatible with the above-described imaging and other well-known positioning methods and which also provides a bumper device mounted on the instrument which, through tactile feedback to the surgeon during introduction and advancement of the instrument, signals when the distal end of the instrument has been properly positioned at a selected location. Positioned proximal to the aortic valve, the bumper device is adapted to conform to gently engage the various anatomical structures of the aortic root without obstructing the coronary ostia or traumatizing the valve, instead providing assisted coaptation of the valve leaflets.

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Such a device is especially needed for surgical interventions which require introduction and precise positioning of instruments into the lumen of the patient's aorta proximal to the aortic root and which must remain fixed in that selected location without displacement or movement until the surgical procedure is completed. Further, it is desirable that such an instrument be capable of preventing the retrograde flow or regurgitation of blood and/or cardioplegia past a partially or fully incompetent native heart valve or valve prosthesis during cardiopulmonary bypass and/or various cardiothoracic surgical interventions, and be capable of delivering antegrade and venting retrograde cardioplegia and of venting the aortic root or left ventricle.

SUMMARY OF THE INVENTION

5 The invention relates to devices and methods for precisely positioning and securing surgical instruments, such as catheters, in and downstream to the aortic root region of the patient's aorta for procedures where it is desirable to isolate the coronary arteries from the rest of the arterial system. The invention also relates to devices and methods for rendering a heart valve, whether natural or prosthetic, in a more closed position thereby preventing the retrograde regurgitation of fluid and blood past the heart valve during surgical interventions, more specifically, interventions where the patient is placed on cardiopulmonary bypass, the lungs are not functioning and the heart is arrested and decompressed.

10 Although the bumper instrument of the present invention is described as incorporating various elements, as will be described more fully below, the invention likewise contemplates lumenless bumper embodiments for aortic valve competence functions. Such bumper only embodiments are further contemplated for use alone or in conjunction with separate surgical instruments including separate balloon catheters and external blood vessel clamps.

15 The aortic catheterization bumper instrument is formed with an elongated shaft or tube device adapted to extend from an external or extracorporeal location, to an operative position in the vasculature of a patient, extendable to a selected location near the aortic root to access the heart through the ascending aorta, while isolating the coronary arteries from the rest of the arterial vasculature. The shaft of the tube device may include a lumen for communicating fluid from a proximal port disposed at the external location to a distal port at a distal end which is adapted to be in fluid communication with the selected location in the aorta. The tube device may also be configured with additional fluid lumens and corresponding ports as well as with lumens, passageways and/or channels adapted for other uses including, but not limited to, slidably receipt of valve and bumper actuators and introduction of additional surgical instruments.

20 The tube device also contemplates externally controllable valves for regulating the fluid flow through either of such ports, the lumen or around the exterior of the shaft between it and the aortic walls. The tube device shaft is preshaped, in the exemplary embodiment, to conform to the curvature of the aorta depending on the method of introduction. For example, if the instrument

5 is to be introduced via a femoral artery, then the distal end of the shaft is generally U-shaped to follow the radius of the arch and the contour of the ascending aorta for placement of the distal end in the aortic root. In another embodiment, the shaft is shaped for introduction directly through the wall of the ascending aorta such that it bends with a tighter "L" or "J"-shaped radius to position the distal end in the aortic root after insertion through the aortic wall.

10 The instrument further incorporates a retractable or collapsible bumper mechanism or device mounted to the distal end which includes bumper elements configured to be retractably deployed outward from said distal end and to softly bump against the aortic root as the instrument is inserted and guided through the patient's aorta. The bumper elements in one embodiment are designed, to be deployed just above, or downstream to, the aortic valve or prosthesis and are configured to correspond with and to conform to the shape of the one or more leaflets of the aortic valve and to hold the valve leaflets, when the bumper device is deployed, in a more closed position. Although most patients have three native valve leaflets, various anatomical variations include native valve and many types of prosthetic valves having one, two 15 or more such leaflets.

20 The bumper elements in another embodiment are preshaped and configured to be inflatable balloons, extendible arcuate spring members, pushers or wires, or extendible, balloon-supporting skeletal wires which, when deployed, conform to the aortic valve leaflets and bias the valve in a more closed position.

25 In yet another embodiment, the bumper elements are configured to form, when deployed, a generally planar, flat poppet or floor valve member which, once deployed, inflates, unfurls or lays flat just above, or downstream to, the aortic valve and conforms thereto to impede the regurgitant flow of fluid in the upstream, or retrograde direction, past the valve and into the left ventricle. This embodiment acts as a poppet type pressure responsive valve that allows flow in one direction while impeding flow in the opposite direction.

Furthermore, the mechanism or device may be further adapted so that a secondary instrument, such as a pigtail catheter, may be introduced through or adjacent to the fluid

communication lumen, passageway or channel to pass by or through the bumper mechanism, across the aortic valve and into the left ventricle for perfusing or aspirating fluids. Such a pigtail catheter device may also be integrally formed with the bumper instrument to be either fixed in position relative to the bumper mechanism or to be extendible across the aortic valve and into the left ventricle. Further, an extendible pigtail catheter device may incorporate the poppet such that once extended, the poppet is deployed downstream of and against the aortic valve. Also, other types of secondary surgical intervention instruments may be introduced, removed and replaced with other instruments, to perform procedures in the coronary arteries, aortic valve and/or the heart. The bumper instrument may also include additional fluid communication lumens or surgical instrument passageways through which the secondary instruments may be introduced and advanced into the patient's vasculature.

The instrument may also include a balloon or a specially formed collapsible catheter position stabilizer-flow regulator (hereafter "CPFR") formed externally on the instrument which, when deployed, is designed to perform at least two functions. First, it operates as a flow regulator or valve mechanism configured to regulate or prevent flow of fluid past the CPFR, in either the upstream or downstream directions, also respectively known as the retrograde or antegrade directions, or to regulate or control flow in both directions for applications requiring complete isolation and prevention of fluid flow past the CPFR. Second, it stabilizes and prevents longitudinal or radial displacement of the instrument when it is in the operative position.

The CPFR contemplated by the invention may be actively or passively actuated, either internally or externally, and may be formed symmetrically about the exterior of the instrument or may be, in certain embodiments, asymmetrically disposed about the exterior of the elongated instrument shaft. The CPFR may be constructed in a number of configurations including, but not limited to, an inflatable balloon, an inflatable or extendible stent-type wire-frame skeleton or an umbrella or conically shaped device which is radially deployed into position from the external circumference of the bumper instrument.

The CPFR may also act in conjunction with or incorporate the above-described poppet type valve configuration to create an isolated chamber within the aortic lumen which isolates the

coronary arteries from the rest of the arterial system and from the left ventricle and other chambers of the heart.

5 In operation, the aortic catheterization bumper instrument is introduced into a peripheral or great blood vessel, typically an artery, of a patient by the Seldinger guidewire technique or by cut-down of the blood vessel or the ascending aorta. With the CPFR and bumper fully collapsed and retracted, the instrument is advanced into the blood vessel lumen to the selected location. Once the instrument has been advanced to a location near the selected location, the bumper device is deployed. Thereafter, the instrument is further advanced until the bumper elements 10 bump against and/or engage either the sinotubular ridge at the downstream edge of the aortic sinuses in the aortic root, the aortic valve annulus, or the individual leaflets of the natural or prosthetic aortic valve. Once the bumper elements have been seated against the ridge, annulus, or valve leaflets, the instrument will no longer advance thus sending tactile feedback to the surgeon to signal that the instrument has been precisely positioned.

15 Further, the instrument may also include strategically positioned markers to augment the tactile feedback with the use of the various imaging techniques described above. Such markers are usually either sonoreflective and/or radiopaque for use with ultrasonic or fluoroscopic equipment, respectively. The markers may also be constructed of high-contrast indicia registrably and/or visually compatible for use with angioscopic, video-fiber-optic, ultrasonic or thermal imaging equipment. Also, the bumper instrument may include integrally formed or adjunctively 20 employed imaging sensors for direct visualization of the placement of the distal end of the instrument at the selected location in the vasculature of the patient.

25 Next, the CPFR or inflatable balloon is either deployed or inflated partially, to operate as a flow regulator, or fully, to seal the aortic lumen and isolate the coronary arteries from the rest of the arterial system. In addition to resisting the flow of fluid past the CPFR, deployment of the symmetrically or asymmetrically shaped CPFR assists in preventing longitudinal displacement of the instrument in two ways. In lumenless and/or non-CPFR embodiments, deployment of a separate balloon or CPFR catheter or external cross-clamp may also be 30 performed.

After the instrument has been introduced and deployed, the patient is typically placed on partial or full cardiopulmonary bypass with a perfusion catheter introduced into the aorta centrally or peripherally above the CPFR for pumping a temperature controlled fluid mixture including oxygenated blood into the aorta above or downstream of the CPFR. The temperature controlled fluid may include cooled or warmed fluid and may also, in some applications, include cardioplegia or resuscitative fluids. The fluid is pumped into the aorta at a flow rate which creates a pressure differential in the aortic lumen above the CPFR that acts as a force biasing the CPFR, and consequently the entire aortic catheterization instrument, in a longitudinal direction towards the aortic root. The bumper device is thereby, in turn, biased against the aortic root or the valve leaflets which aids in keeping both the valve in a more closed position and the instrument from wandering in a longitudinal direction in the aortic lumen.

As a second contributing factor to preventing displacement, the CPFR is formed with an outer surface having either a specialized coating or a particular shape operative to, when the CPFR is fully deployed, atraumatically engage the internal aortic lumen walls to resist relative movement of the CPFR. Further, the bumper elements may be preshaped to, when deployed, engage the aortic annulus or the sinotubular ridge, among other anatomical aortic structures.

Deployment of the CPFR also serves an important function in limiting dispersion of emboli which may be released into the bloodstream by interventions performed upstream of the CPFR. When fully deployed, the CPFR prevents any fluid or blood flow past the point where it has sealed the lumen of the blood vessel. In this configuration, the isolated portion of the blood vessel lumen may be repeatedly irrigated and aspirated to remove any embolic debris from the isolated region.

In situations where the CPFR is not to be fully deployed, the bumper instrument may incorporate an integral filter device, or may be employed with an adjunctive filter instrument. In either case the instrument positions a filter member downstream of the CPFR which is deployed to fully extend radially within the blood vessel lumen to capture any embolic debris which may have been loosened from the walls of the blood vessel due to the deployment of either the bumper mechanism or the CPFR. Such a filter member would be porous to blood and fluids but impermeable to embolic debris and may be configured in a windsock configuration with a vent

catheter incorporated at a downstream cusp of the windsock filter member for periodic or continuous aspiration of embolic material from the filter. Such filters are described and disclosed in more detail in commonly owned, copending U.S. Provisional Application Serial No. 60/060,117 filed on September 26, 1997 which is hereby expressly incorporated by reference in its entirety.

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Accordingly, it is an object of the present invention to provide an aortic catheterization bumper instrument to be introduced and advanced into an operative position within a lumen of a patient's vasculature to a selected location without the necessity for exclusive monitoring with various imaging technologies and which, through tactile and enhanced imaging feedback, signals that it has been fully introduced and precisely positioned in the selected location in the lumen, such as, for example the aortic sinus or aortic root region of the ascending aorta. Such precise positioning includes predetermined placement, once the instrument is fully introduced, of the CPFR downstream of the coronary arteries with the bumper elements in a non-obstructing, upstream position relative to the ostia of the coronary arteries.

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It is a further object of the invention to isolate the coronary arteries of the heart from the rest of the arterial vasculature, while maintaining extracorporeal fluid communication with the coronary arteries, without the need for traumatic cross-clamping of the aorta. Cross-clamping the aorta can result in trauma and the unexpected release of emboli into the blood stream in patients having, for example, atheromatous or calcific disease of the aorta. The fluid communication capability is adapted for delivery of cardioplegia into the coronary ostia or drainage from the ostia, aortic root and/or left ventricle.

20

Another object of the invention is to incorporate a bumper device having elements which atraumatically render an incompetent native or prosthetic aortic valve more competent by maintaining the leaflets of the valve in a more closed position to prevent regurgitation of blood and fluid past the valve and into the left ventricular cavity.

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5 Although in certain embodiments, and for particular procedures, an external cross-clamp may be used, the bumper device invention is also intended to sealingly engage the walls of the blood vessel lumen atraumatically and to prevent the release and downstream dispersion of embolic material and to facilitate the capture and aspiration of inadvertently released embolic material downstream of the flow regulator.

10 Also, it is an object of the invention to ensure that the aortic catheterization instrument is restrained to prevent longitudinal or radial displacement once it has been precisely positioned in an operative position within the lumen of the blood vessel.

15 These and other objects and advantages of the present invention will become more apparent from the following detailed description of the invention when considered in conjunction with the accompanying exemplary drawings. Such drawings are provided for purposes of illustration only and are not intended to limit the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

20 Referring now to the drawings, wherein like reference numerals across the several views refer to identical, corresponding or equivalent parts:

25 FIG 1 is a perspective view of the exemplary embodiment of an aortic catheterization bumper instrument, which incorporates the aortic valve bumper device constructed in accordance with the principles of the present invention including a CPFR.

30 FIG 2 is a perspective view of the exemplary embodiment of FIG 1 configured for use with an aortic cross-clamp.

35 FIG 3 is a perspective view, in reduced scale, showing the aortic valve bumper device of FIG 1 in a fully retracted configuration without the CPFR.

40 FIG 4 is a perspective view, in reduced scale, showing the aortic valve bumper device of FIG 1 in a deployed configuration without the CPFR.

45 FIG 5 is a side view, in reduced scale, of the aortic valve bumper device of FIG 3.

50 FIG 6 is a side view, in reduced scale, of the aortic valve bumper device of FIG 4.

FIG 7 is a perspective view of another embodiment of the aortic valve bumper device of FIG 1 with separate bumper elements.

FIG 8 is a side view, in reduced scale, of another embodiment of the aortic valve bumper device of FIG 6.

5 FIG 9 is a side view, in reduced scale, of another embodiment of the aortic valve bumper device of FIG 6.

FIG 10 is a perspective view of the aortic catheterization bumper instrument incorporating another embodiment of the aortic valve bumper device of FIGS 1, 7 and 9.

10 FIG 11 is a side view, in reduced scale, of another embodiment of the aortic valve bumper device of FIG 6.

FIG 12 is a side view, in reduced scale, of another embodiment of the aortic valve bumper device of FIG 6.

FIGS 13, 14, 15 and 16 are side views, in reduced scale, of another embodiment of the CPFR shown in FIGS 1, 7 and 10.

15 FIGS 17 and 18 are perspective views of an alternative embodiment of the aortic catheter bumper instrument of FIGS 1, 7 and 10 having a modified catheter position stabilizer-flow regulator and bumper mechanism.

20 FIGS 19 and 20 are perspective views of another alternative embodiment of the aortic catheter bumper instrument of FIGS 1, 7, 10, 17 and 18 having a modified catheter position stabilizer-flow regulator and bumper mechanism.

FIGS 21 and 22 are perspective views of an additional alternative embodiment of the aortic catheter bumper instrument of FIGS 1, 7, 10, 17 and 18 having a modified catheter position stabilizer-flow regulator and bumper mechanism.

25 FIGS 23 and 24 are perspective views of an alternative embodiment of the aortic catheter bumper instrument of FIGS 1, 7, 10, 17 and 18 with a modified catheter position stabilizer-flow regulator and bumper mechanism.

FIGS 25 and 26 are perspective views of a further alternative embodiment of the aortic catheter bumper instrument of FIGS 1, 7, 10, 17 and 18 constructed according to the principles of the present invention.

30 FIGS 27 and 28 are perspective views of a variation of the instrument of FIGS 25 and 26.

FIGS 29 and 30 are side views, in enlarged scale, of a variation of the embodiment of FIGS 27 and 28.

FIGS 31 and 32 are side views, in enlarged scale, of another variation of the embodiment of FIGS 27 and 28.

5 FIGS 33 and 34 are perspective views of another alternative embodiment of the aortic catheter bumper instrument of FIGS 1, 7, 10, 17 and 18 constructed according to the principles of the present invention.

10 FIGS 35 and 36 are perspective views of an alternative embodiment of the aortic catheterization bumper instrument of FIGS 1, 7, 10, 17 and 18 constructed according to the principles of the present invention.

FIG 37 is an alternative embodiment of the aortic catheterization bumper instrument configured for introduction via a femoral artery approach.

15 FIG 38 is an alternative embodiment of the aortic catheterization bumper instrument that includes two CPFR balloons configured for the femoral approach.

FIGS 39 and 40 are schematic diagrams of the specific webbed bumper device used in FIGS 37 and 38 depicted as a top and side view respectively.

20 FIG 41 is an alternative embodiment of the aortic catheterization bumper instrument including a CPFR for perfusion of the arch vessels configured for introduction via a subclavian artery approach.

FIG 42 is a variation to FIG 41 where the CPFR is in the form of a valve.

25 FIG 43 is a perspective view of another embodiment of the aortic valve bumper device of FIG 1 with preshaped retractable bumper elements.

FIG 44 is a perspective view of another embodiment of the aortic valve bumper device of FIG 1 with preshaped retractable bumper elements and a pigtail-type venting catheter.

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DETAILED DESCRIPTION OF THE INVENTION

The invention is a precision engineered aortic catheterization bumper instrument for use in performing cardiovascular, cardiopulmonary and neurovascular surgical. Also contemplated is use of and compatibility of this invention with the main stage catheterization instrument

disclosed in commonly owned, copending U.S. Provisional Application Serial No. 60/060,127 filed on September 26, 1997 which is hereby expressly incorporated by reference in its entirety.

The instrument can be precisely positioned in a lumen of a patient's vasculature with or without the aid of imaging techniques such as transesophageal echocardiography, fluoroscopy, 5 angioscopy, and others. The instrument is introduced into a lumen, such as the aortic lumen, by minimally invasive percutaneous insertion techniques without the need for performing either a thoracotomy or a cutdown of a target blood vessel with the chest open, although it is also compatible for use with such procedures. The instrument can be also be configured for insertion into a peripheral vessel, such as the femoral artery, and advancement up through the descending aorta until a selected location is reached. Typically, the selected location is a position in the 10 lumen where a surgical procedure is to be performed.

The bumper device of the invention can be adapted for compatibility with a wide variety of surgical instruments which require precise positioning through tactile and enhanced imaging feedback to signal when, as the instrument is advanced into an operative position in the blood 15 vessel lumen, the precise, intended position has been achieved. The invention includes, as described in more detail below, a catheter position stabilizer-flow regulator (hereafter "CPFR") which prevents longitudinal and radial movement of the instrument when it is inserted in the operative position. Also, the instrument includes one or more specially constructed bumper element(s) for biasing a natural or prosthetic heart valve in a more closed position and for rendering an incompetent natural or prosthetic heart valve more competent to prevent and/or 20 minimize the retrograde regurgitation of fluid and blood past the valve when the instrument is deployed.

Referring now to FIG 1, one example of an embodiment of the aortic catheterization bumper instrument of the present invention is indicated generally by reference numeral 10 and is intended for precise positioning in the lumen of the ascending aorta of the patient. The bumper 25 instrument 10 incorporates an elongated shaft or tube device 15 which, when inserted in an operative position 20, extends between a location 25 external to the aortic lumen, and/or the patient's body, and a selected location 30 disposed in the aortic lumen 35 just below the ostia of

the coronary arteries 36 and above, or downstream to, the aortic root 38 downstream of the natural or prosthetic aortic valve 42 of the patient's heart 40.

Two of the aortic valve leaflets 44 are shown in cross-section in FIG 1 just below the aortic root 38. The tube device 15 is formed with a fluid communication lumen 45 extending between a proximal port 50 disposed at the extracorporeal and/or external location 25 and a distal port 55 formed in an internal distal end 60 of the instrument 10. Additional fluid flow lumens, actuator channels or secondary instrument passageways, not shown, may be incorporated in alternative embodiments of the tube device 15 without departing from the intended scope and breadth of the invention. Also not shown in the figures are fluid flow control valves that may be incorporated in the tube device 15 to control the fluid flow through either of the respective ports 50, 55 or through the lumen 45. Such valves include, but are not limited to, sheath obturators slidable over the port 55, lumen attenuators, and pressure actuated valves which remain closed until, for example, the lumen 45 is pressurized to a predetermined valve actuation pressure. Additionally, the lumen 45 and/or the ports 50, 55 may be fabricated to have predetermined sizes relative to one another to limit the potential maximum rate of fluid flow therethrough for a given perfusate composition and temperature at a given pressure in the lumen 45.

The elongated shaft of the tube device 15 is formed with either a single lumen or multilumen construction and is preferably extruded of a non-thrombogenic, non-hemolytic, flexible thermoplastic material or a thermoplastic elastomer. Suitable materials include, but are not limited to, polyvinyl chloride, polyurethane, polyethylene, polypropylene, polyamides (nylons), and alloys or copolymers thereof, as well as braided, coiled or counterwound wire or filament reinforced composite materials. In an exemplary embodiment of FIG 1, the single fluid communication lumen 45 extends from the proximal end 50 to the distal end 60 where the communication lumen 45 opens to port 55.

In a variation of this embodiment, the distal end 60 has either a simple beveled or rounded distal edge with an opening therethrough for fluid communication with the blood vessel lumen or it may include additional side ports or a flow diffuser to reduce jetting or blockage of suction when a fluid, such as blood is infused or aspirated through the fluid communication

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lumen 45. The proximal end 50 of the elongated shaft 15 is adapted for connecting the fluid communication lumen 45 to a cardiopulmonary bypass pump or other source of vacuum or perfusate using standard polycarbonate or rigid polyurethane barb connectors or other connectors, such as a standard luer fitting (not shown). The proximal end 50 may also incorporate a sliding hemostasis valve or valves (not shown) for minimizing loss of fluid from the proximal end 50 during introduction, advancement or removal of secondary instruments to the selected location through either the fluid communication lumen 45 or other lumens, channels or passageways which may be incorporated into variations of the exemplary embodiment or into alternative embodiments.

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Preferably, the tube device 15 is fabricated to have a thin walled construction to maximize the internal diameter and therefore the flow rate of the fluid communication lumen 45 for a given outside diameter and length of the tube device 15. Thin walled construction also allows the outside diameter of the tube device 15 to be minimized in order to reduce the invasiveness of the surgical intervention and to reduce the trauma at the insertion site. The fluid communication lumen 45 may be, for certain cardiopulmonary bypass applications, configured to allow sufficient blood flow to preserve organ function without hemolysis or other damage to the blood. For standard cardiopulmonary support techniques, the shaft of the tube device 15 is constructed to have an outer diameter of 18-24 French size (6-8 millimeters outside diameter) which is sufficient to deliver approximately 3-5 liters of oxygenated blood to the patient's body to preserve organ function. For applications of the bumper instrument directed to other uses, such as establishing and maintaining cardiac arrest while other instruments are employed to effect cardiopulmonary bypass, the outer diameter of the tube device 15 may be substantially smaller. Conversely, for such applications where other instruments are employed concurrently and introduced through tube device 15, its outer diameter may be substantially greater. For low flow cardiopulmonary support techniques, such as that described in co-owned, copending U.S. Patent Application serial no. 06/084,835 filed on May 5, 1998 which is hereby incorporated by reference in its entirety, the size of the tube device 15 can be reduced even further to accommodate the lower flow rates of oxygenated blood or other sustaining fluid mixtures.

5 The tube device shaft 15 has a length sufficient to reach from the external, peripheral access point where it is inserted to the selected location in the blood vessel of the patient. For femoral artery introduction to a selected location in the ascending aorta close to the aortic root, the length is preferably approximately 80-120 centimeters. A length of approximately 60 centimeters is adequate for antegrade insertions through the wall of, for example, the ascending aorta. Other lengths can be established for insertions into other neck, arm, leg or corporeal blood vessels.

10 The tube device shaft is preshaped for optimum compatibility with the selected insertion procedure. For purposes of illustration, the tube device shaft 15, as shown in FIG 1, has a generally "J" or "L"-shaped preformed curvature to facilitate insertion through the wall of the ascending aorta such that the distal end 60 bends downward as it is advanced towards the aortic root 38 to place the distal end 60 just above, or downstream to, the aortic root 38.

15 Positioned at the distal end 60 is a bumper mechanism or device 65 which, in the exemplary embodiment, is shown with multiple inflatable bumper elements 70. In this and other embodiments, the bumper device 65 may be constructed so that the multiple bumper elements 70 are inflated or otherwise deployed selectively and individually, or they may be inflated or deployed jointly and simultaneously. Alternatively, the bumper device 65 may be constructed with a single bumper element 70 that, when inflated or otherwise deployed, creates multiple lobes on its distal surface to conform to the leaflets 44 of the aortic valve 42. The bumper elements 70 are preferably fabricated either from a flexible, but inelastic or non-distensible, material or from a combination of such material and a thin wire frame or mesh which forms a skeleton upon which the bumper material is supported, as will be shown in later described embodiments. The bumper 65 may also be configured with one or more such bumper element(s) 70 to correspond with and engage a particular patient's aortic root, annulus, sinotubular ridge or valve configuration. For example, even though the majority of patients have three aortic valve leaflets, some patients may have an aortic valve with either one or more valve leaflets while others may have a valve prosthesis implanted. In such patients, the bumper 65 may need to be configured according to the particular patient's native anatomical or prosthetic valve configuration so as to 1) prevent damage to the valve or the aortic root and 2) ensure

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compatibility of the instrument with the particular configuration of the valve and aortic root. For example, the bumper device may be configured with a single bumper element 70 which is adapted to correspond with a single leaflet anatomical variant of the more common three leaflet aortic valve. In any variation of the exemplary embodiment, the outer circumferential diameter of the deployed bumper 65 is preferably sized to engage anatomical aortic structures having average internal, cross sectional diameters approximately in the range of 2-3 centimeters, to accommodate the normal human adult range of internal aortic luminal, root, annulus and sinotubular ridge diameters. Smaller and larger diameters are indicated for pediatric patients and for very large patients respectively.

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Optionally, instrument 10 is also formed with a bumper element actuator 75 which is adapted to independently or simultaneously deploy and retract the corresponding bumper element(s) 70. The actuator 75 extends along the tube device 15 from the external location 25 to the distal end 60. In the exemplary embodiment shown in FIG 1, the bumper device 65 incorporates bumper element(s) 70 which are fabricated as inflatable balloons. In alternative embodiments which include more than one bumper element 70, multiple corresponding actuators 75 may be incorporated being operative to individually control each bumper element 70.

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The balloon bumper element(s) 70 can be preshaped and sized to conform to and/or to atraumatically engage the aortic root 38, the sinuses of Valsalva, the aortic valve annulus 39 and/or the sinotubular ridge. The balloon element configuration may include either a single balloon element or as one or more individual balloon elements configured to correspond to and naturally seat with the cusps of the one or more aortic valve leaflets 44. In the exemplary embodiment, the bumper element(s) 70 are preshaped and sized to engage the aortic annulus 39 of the patient so as to aid in preventing the inadvertent longitudinal displacement of the bumper instrument 10 after it has been fully introduced to the selected location. Many size and shape configurations of the bumper elements 70 are contemplated to establish compatibility of the bumper instrument 10 with the many anatomical variations of aortic roots and native or prosthetic valves, whether such valves are aortic or disposed in other anatomical locations. The bumper device 65 may be fabricated from many suitable non-toxic, hemocompatible, or non-thrombogenic and non-hemolytic, materials such as Tecothane 1080A polyurethane, which is

thermobonded or adhesively bonded to the exterior of the shaft circumference and is preshaped to collapse about the exterior circumference of the tube device shaft 15. Other possible materials include, but are not limited to, latex, silicone, polyvinylchloride, polyethylene, nylon, ethylene vinyl acetate, polyester and other polymeric and elastomeric materials.

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Optionally, the tubular shaft 15 of the bumper device 65 be constructed as a torque catheter or may incorporate a separate torque catheter slidably and rotatably received about the exterior of the tube device 15 or concentrically received within the fluid communication lumen 45. Such a torque catheter may be constructed with a wire reinforced or wire or filament braided or wound shaft. The torque catheter is connected at its distal extremity to the bumper elements 70 and extends to a proximal extremity disposed at the external location 25. In addition, the torque catheter is configured in a variation of this embodiment as a bumper element actuator operative to deploy and retract, or collapse, the bumper elements 70. The torque catheter is configured to, upon rotation of its proximal extremity at the external location 25, to correspondingly rotate the bumper elements 70 about a central, longitudinal axis of the blood vessel lumen 35, so as to collectively reposition the individual bumper elements 70 to positionally correspond with a respective individual valve leaflet 44. This adjustment ensures that the bumpers 70 naturally seat into the cusps of the aortic valve leaflets 44.

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Visualization of the position of the bumper elements 70 and the valve leaflets 44 is accomplished in any number of ways which have been previously mentioned above. In the exemplary embodiment, verification of the proper position of the bumpers 70 is established visually by angioscopy, ultrasound imaging, or by fluoroscopy, if the latter is available. The multi-lobed structure of the bumper elements 70 incorporates markers, as described in more detail below, which are recognizable by the various types of imaging equipment, in all of the various embodiments and variations. In one group of alternative embodiments described below, the bumper elements are constructed with wires which are easily recognized on the visual displays of the monitoring equipment. In the exemplary embodiment, variations are incorporated to augment visualization of the bumper elements 70. Sonoreflective, radiopaque and/or high-contrast visual indicia markers are incorporated into the structure of the bumper elements 70 to enhance the registrability of the elements 70 on the visual displays of the respective types of

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5 monitoring equipment. The markers are strategically positioned on each individual bumper element 70 for maximum visibility such that the bumpers 70 may be easily adjusted to correspond with a respective leaflet 44. Additionally or alternatively, the tube device 15 and/or the bumper elements 70 may also include an aortic transillumination system using optical fibers and/or light emitting diodes or lasers for locating and monitoring the position of the device within the patient's aorta. Such an aortic transillumination system is described in more detail in commonly owned, copending U.S. Provisional Patent Application 60/088,652, filed June 9, 1998 which, along with its corresponding utility patent application, is hereby incorporated by reference in its entirety.

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15 In another variation of this embodiment, the balloon may be fabricated from a material specially impregnated with a sonoreflective or radiopaque substance such that the entire platform of the bumper elements 70 are visually registered on the monitoring equipment. Also, once the bumper elements 70 are respectively positioned and seated into the leaflet cusps, radiopaque dye may be injected into the isolated aortic sinus region for fluoroscopic detection of transvalvular regurgitant fluid in the left ventricle to verify whether or not the valve is closed. Although not described below with respect to each of the following embodiments, the torque catheter is contemplated for use with all of the embodiments and variations of the present invention.

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25 The bumper mechanism 65 of the exemplary embodiment for bumping against and/or engaging the aortic root 38 and/or valve leaflets 44 is described in detail for illustration purposes only and is not intended to limit the configuration of the bumper elements 70. The bumpers 70 may also be specially shaped to bump against other vasculature or heart structures to signal the same tactile feedback to establish precise positioning without the need for exclusive reliance on the above-described monitoring techniques. The bumper mechanism 65 and its bumper elements 70 may be configured to bump against and register with branch vessel ostia, chambers and structures of the heart reached by transvalvular advancement of the bumper instrument 15 into the heart 40.

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Also, the bumper elements 70 can be configured to register with specific regions of blood vessels having known inner diameters at a selected location, transitional diameters and known

changes in direction such as, for example, the region where the inferior vena cava transitions to the superior vena cava, the region where the aortic arch transitions downwardly into the ascending aorta, and the region of the right ventricle which transitions into the ostium of the coronary sinus. It can be understood by one of ordinary skill in the art that the bumpers 70 may be modified in any number of possible combinations to facilitate compatibility with the various vascular and cardiac anatomical structures to render the bumper instrument 10 compatible for use in a wide array of applications. The CPFR 80 is also shown in FIG 1 and is mounted to the instrument 10 about the shaft 15 between the distal end 60 and the proximal port 50. The CPFR 80 of the exemplary embodiment is an inflatable balloon 90 which, when inflated, atraumatically pushes against the walls of the aortic lumen to stabilize and center the distal end 60 in the aortic lumen 35 to prevent radial displacement of the distal end 60 and the bumper device 65 and also to stabilize the longitudinal position of the instrument 10 in the blood vessel lumen to prevent longitudinal displacement once it has been advanced to the selected location 30.

The CPFR inflatable balloon 90 of this exemplary embodiment is formed about the exterior circumference of the tube device shaft 15 to be disposed proximally from the distal end 60. The CPFR 90 may be fabricated from many suitable non-toxic, hemocompatible, or non-thrombogenic and non-hemolytic, materials such as Tecothane 1080A polyurethane, which is thermobonded to the exterior of the shaft circumference and is preshaped to collapse about the exterior circumference of the tube device shaft 15. Other possible materials include, but are not limited to, latex, silicone, polyvinylchloride, polyethylene, nylon, ethylene vinyl acetate, polyester and other polymeric and elastomeric materials. The interior of the CPFR 90 is in fluid communication with an inflation port formed in the tube device 15 which opens to an inflation lumen extending to the proximal end 50 at the external location 25. Alternatively, the CPFR material may be fabricated from a non-distensible material and preformed to have a pleated, collapsible shape which is also compatible for introduction, advancement, inflation, collapse and removal. The non-distensible and distensible variations are both adapted to have a maximum outer diameter configured to, when fully inflated, to sealingly and atraumatically engage the walls of the blood vessel lumen. The non-distensible variation reaches a maximum inflation configuration having a maximum outer diameter which does not change with a corresponding increase in the inflation pressure.

5 In contrast, although similar in design, the distensible variation reaches a maximum outer diameter at a predetermined inflation pressure above which, the balloon expands only in the upstream and downstream longitudinal directions. In any variation of the exemplary embodiment, the outer circumferential diameter of the inflated or deployed CPFR 80 is preferably sized to engage anatomical aortic structures having average internal, cross-sectional diameters approximately in the range of 1-5 centimeters in diameter and more preferably approximately in the range of 2-3 centimeters, to accommodate the normal human adult range of internal aortic luminal diameters. Smaller and larger diameters are indicated for pediatric 10 patients and for very large patients, respectively.

15 While in the exemplary embodiment the CPFR 90 is fixed in position relative to the distal end 60, an alternative embodiment (not shown) is configured for longitudinal displacement of the CPFR 80 about the exterior of the tube device 15 by external control. In this variation, the CPFR 80 is connected to the internal end of an actuator shaft and is slidably received into a longitudinal channel formed in the exterior circumference of the tube device shaft 15 and extending to the external location 25. Alternatively, the CPFR 80 is mounted to a distal end of a tubular catheter slidably and concentrically formed about the exterior of the tube device 15. The tubular catheter or the actuator is slidable independently of the tube device 15 such that the CPFR 20 80 is longitudinally positionable relative to the tube device 15. This configuration is adaptable for use with all of the previously and later described embodiments of the bumper devices and CPFR's.

25 The CPFR 80 also operates as a blood and fluid flow regulator, when partially deployed or inflated, and as a flow isolator or blocker, when fully deployed or inflated, to block the flow of blood through the aortic lumen to, in turn, isolate the coronary arteries 36 from the rest of the arterial system. When the CPFR 80 is fully deployed or inflated, the bumper instrument 10 operates as a coronary artery isolator catheterization and bumper instrument. When the instrument 10 has been fully advanced to the selected location 30, the deployed bumper 30 element(s) 875, depending on their preconfigured size and shape, atraumatically either bump against and/or engage the aortic root 38, or sinotubular ridge 39, or bump against the one or more

leaflets 44 of the aortic valve 42. Bumping against either or both of these anatomical structures prevents further advancement of the instrument 10 and gives tactile feedback to the surgeon signaling that the instrument has been precisely positioned to the selected location 30.

5 The instrument further incorporates a CPFR actuator, which in the exemplary embodiment is an additional lumen 91 that is formed in the tube device 15. The lumen extends from a balloon port 85, which is in fluid communication with the interior of the balloon 90, to the external location 25 for communicating a gas, e.g. CO₂, or fluid, such as saline, to inflate and deflate the balloon 90. In alternative embodiments, the CPFR actuator is alternatively configured as, for example, an extensor or retractor shaft, which is actuatable from the external location 25 for deployment and retraction of the CPFR.

10 A variation of the CPFR of the exemplary embodiment incorporates one of several similar variations of material to achieve a weeping CPFR configuration capable of perfusing a fluid at a predetermined rate of flow for a given inflation pressure. In this variation, as exemplified by FIGS 11 and 12 either or both the upstream or the downstream surface of the CPFR is formed with a material having a precalibrated porosity with respect to a preestablished maximum inflation pressure and type of perfusate. The perfusate can include a mixture of, for purposes of illustration, blood and crystalloid cardioplegia. When inflated, the weeping CPFR configuration is adapted to deliver a precalibrated flow rate of fluid into either or both the upstream or downstream region, with respect to the CPFR, of the blood vessel lumen. By way of example, the upstream side of the CPFR is formed from a micro-perforated Tecothane 1080A polyurethane material. Once the CPFR has been fully inflated with perfusate to a predetermined inflation pressure, perfusate passes from within the CPFR to the upstream side at a precalibrated rate of flow. One of the many benefits of this weeping balloon configuration is that the fluid communication lumen of previous embodiments can be used, as an example, for perfusing a second composition or temperature fluid, for irrigating and aspirating fluids and to act as a saline filled, pressure-sensing lumen.

15 20 25 30 These and other alternative configurations and embodiments of such CPFR's are described in more detail, with respect to some features and elements, in co-owned, copending

U.S. Provisional Patent Application serial no. 60/060,158, filed on September 26, 1997 and in U.S. Patent Application serial no. 08/664,361 filed on June 17, 1996 which are each hereby incorporated by reference in their entirety.

To aid in precision positioning of the bumper instrument 10 during advancement into the patient's aortic lumen or other blood vessel, strategically placed sonoreflective, radiopaque, fiber-optically reflective, or thermally registrable markers, not shown but well-known in the art and which are designed to be visually compatible with a variety of imaging techniques, may be positioned on the distal end 60 of the bumper instrument 10 to enhance the visibility of the instrument on various types of imaging monitors. Such imaging technologies include use of flourososcopic, ultrasonic, fiber-optic, and infrared sensing devices. While the tactile feedback of the invention serves as the primary means for ensuring precision positioning of the instrument, the combination of tactile feedback and enhanced visual registration of the marker on the distal end 60 of the instrument 10 on the visual displays of the imaging and monitoring equipment further improves the surgeon's ability to precisely position the instrument. Further, such markers can be integrally formed into the instrument 10, as previously illustrated. Additionally or alternatively, the tube device 15, the bumper elements 70 and/or the CPFR 80 may also include an aortic transillumination system using optical fibers and/or light emitting diodes or lasers for locating and monitoring the position of the device within the patient's aorta, as described in U.S. Provisional Patent Application 60/088,652, which has previously been incorporated by reference.

In this exemplary embodiment, the bumper elements 70 have been preshaped and presized to, when inflated or deployed, bump against and conform to the leaflets 44, to atraumatically bias the valve 42 in a more closed position until either the bumper elements 70 have been retracted or until the instrument 10 is removed. Confirmation that the valves are adequately closed or more closed is accomplished by perfusing a radiopaque or sonoreflective fluid into the aortic sinus region and observing whether regurgitant, transvalvular fluid flow is present by observation of the various monitoring equipment visual displays as previously described.

Alternatively, verification of valve closure can also be achieved by insertion of an 30 angioscope or fiber-optic-type, video compatible sensor into the previously vented left ventricle

to confirm the absence of any appreciable amount of regurgitant fluid flow. The bumper element(s) 70 may be further deployed or inflated, if preferred or necessary, to atraumatically engage the aortic annulus 39 to further aid in preventing longitudinal displacement of the bumper instrument. Additionally, as previously discussed, this configuration of bumper elements 70, when inflated and advanced to seat against the cusps of the leaflets 44, will atraumatically bias the leaflets 44 in a more closed position to render an incompetent valve more competent which, in turn, prevents or impedes the transvalvular regurgitation of fluid into the left ventricle of the heart.

In an alternative embodiment of the present invention, the incompetent valve may also be rendered more nearly competent, in certain patients, if the element(s) 70 are preshaped so as to, when inflated, atraumatically impose a predetermined stretch upon the aortic annulus 39 of the aortic root 38, which, in turn, operates to more nearly close the aortic valve 42 to its natural fully closed position by stretching and/or adjusting the valve leaflets 44.

In further illustrative variations of the exemplary embodiment, biasing the valve 42 in the more completely closed position is required when the valve is partially or completely incompetent and where the patient is to be placed on cardiopulmonary bypass, with the coronary arteries of the heart having been isolated from the rest of the arterial system by deployment of the CPFR 80, so that the heart can be arrested and decompressed. Once the heart is isolated, it is then arrested by perfusion of a temperature controlled mixture of cardioplegia and blood to the coronary arteries 36 from the external location 25 through the distal port 55. The heart is arrested to facilitate various cardiothoracic surgical interventions including, for example, valve repair or replacement, such as implantation of a prosthesis, and revascularization or coronary artery bypass graft procedures.

Similarly, it is often desirable to close the aortic valve 42, where cardioplegia and/or blood, which has been administered into the aortic lumen in a retrograde flow perfusion procedure from the coronary sinus, or in other antegrade perfusion procedures well-known to the art, is to be vented either from the aortic root 38, through the distal port 55, or from the left ventricle through a pigtail catheter advanced through the aortic valve 42, while the valve 42 is

5 biased in a closed position, to the external location 25. As discussed above, the left ventricle may also be vented, without the use of a pigtail catheter, by port 55 in embodiments of the bumper instrument which are configured for advancement through the aortic valve 42 and into the left ventricle to bump against predetermined structures in the heart. Venting and aspiration of fluid from the left ventricle is performed for several purposes including for decompression of the heart in preparation for surgical interventions thereon, for aspiration of regurgitant fluid, for irrigation and aspiration of a heart chamber to facilitate visualization by creating a bloodless intracardiac surgical field, and to unload a failing heart to allow healing or treatment.

10 The above-described embodiment of FIG 1 is also compatible for use without the CPFR. Such a simplified variation of the exemplary embodiments is useful for applications such as that depicted in FIG 2 where an aortic cross clamp 81 is employed to isolate the heart and coronary arteries from the rest of the arterial vasculature as well as FIG 37 where the femoral approach is used. In the femoral approach multiple catheters may be used in addition to the bumper device 15 depending upon the surgical procedure needed.

20 The instrument 10 is shown again in FIGS 3 and 4 in a simplified construction for purposes of clarification. Although the cross clamp 81 may be employed with this variation, incorporation of a CPFR is also contemplated. In this figure, the instrument 10 has been introduced and advanced close to the selected location 30 in the lumen 35 with the bumper elements 70 fully collapsed or retracted. As can be seen in FIG 4, the instrument has been advanced to the operative position 20 and the bumper elements 70 have been fully deployed to be disposed against the leaflets 44 of the aortic valve 42. The respective configurations of the retracted and deployed bumper elements depicted in FIGS 3 and 4 are shown again, in cross-section, in FIGS 5 and 6, respectively. In these figures, the preshaped conformability of the bumper elements seated naturally in the cusps of the aortic valve leaflets 44 is schematically represented for purposes of illustrating the principles of the present invention.

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30 Referring now to FIG 7, another embodiment of an aortic catheterization instrument 710 is shown which is configured similarly to instrument 10 but includes independently deployable bumper elements 770 as part of the bumper device 765. In this configuration, each of the bumper

elements 770 are inflatable balloons which are inflatable through independent inflation lumens 775 which are, in turn, connected to tubular retractors 775' adapted to inflate the bumper elements 770 as well as to forward deploy and retract them. The balloons may be fabricated either from a flexible but inelastic or non-distensible material or from a combination of such material and a thin wire frame or mesh which forms a skeleton upon which the bumper material is supported. The skeletal structure imparts added rigidity to the bumper device which may be required for interventions involving abnormal, diseased, or otherwise less flexible valve leaflets 44. In such situations, closure of the leaflets 44 with the bumper device can require greater bias from the bumper device 765 to improve valve closure or competence and thereby reduce or prevent retrograde regurgitation of blood or fluid past the valve 42. In a patient with a normal valve, such biased closure of the valve 42 by the bumper device 765 may also be desirable where a vent catheter 795, in this case a pigtail-type venting catheter is advanced through the fluid communication lumen 745, shaft 715, past the aortic valve 42, into the left ventricle of the heart and into a venting position in the left ventricle for decompression of the heart 40, and for continued aspiration of the left ventricle. The independently operable bumper elements 775 are also capable of accommodating the various native and prosthetic valve geometries wherein if a single or dual leaflet valve geometry is presented, one or two of the bumper elements 775 may be deployed and/or inflated for compatibility with respective valve configurations.

FIGS 8 and 9 respectively illustrate a side view of the wire mesh 872 and the arcuate spring wire frame member 973 bumper mechanism configurations discussed above. It can be observed from FIG 8 that the wire mesh 872 configuration can be fabricated with or without the flexible, inelastic material which forms the balloon bumper element(s) 770. The mesh configuration 872 also has the advantage that it will not block the ostia of the coronary arteries 36 and can therefore be adjusted longitudinally in the aortic lumen 35 to either close the valve 42 or to partially allow the valve to open, with limited deflection of the leaflets 44, while the heart 40 is ejecting.

The wire mesh 872 and wire frame members 973 can be formed using an elastic or superelastic material or shape memory material, such as a nickel/titanium alloy, to construct the filter support structure and/or the actuation members. The transition temperature of the shape

5 memory material should be chosen to be close to normal body temperature so that extreme temperature variations to achieve malleability or to recall the stored shape will not be necessary for the respective retraction or deployment of the elements formed from the material. The shape memory material of the wire structures should be annealed in the deployed position to confer a shape memory in this configuration. Then, the wire mesh 872 or frame 973 should be cooled below the transition temperature of the shape memory material, so that the wire support structure is malleable and can be shaped into a collapsed position. Depending on the transition temperature, this can be done at room temperature or in iced saline solution.

10 The wire mesh 872 or frame 973 can be retracted into the tube device to facilitate instrument insertion and to avoid premature deployment of the bumpers. Once the instrument is in position within the patient's blood vessel, the bumper structure is deployed and is heated above the transition temperature to deploy the bumpers 872, 973. Depending on the transition temperature of the shape memory material, the bumper structure can be passively heated by body heat (accounting, of course, for decreased body temperature during hypothermic 15 cardiopulmonary support methods) or it can be self-heated by applying an electrical current through the bumper wire structure. When heated, the bumper structure expands to its annealed configuration within the blood vessel. After use, the bumper is returned to the collapsed position by retraction into the tube device of the instrument. This adaptation for incorporating preshaped 20 wire elements is contemplated for all embodiments and variations of the present invention.

25 In FIG 10, another embodiment of the instrument is shown generally by reference numeral 1210. In this configuration, the wire frame 973 configuration shown in FIG 9 is configured without the bumper balloon material depicted as 1270. To achieve such shape memory, the elements 1270 may also be formed to incorporate integral wire frame elements in fabricating the bumper elements 1270. The integral wire frame elements are themselves formed using an elastic or superelastic material or shape memory material, such as a nickel/titanium alloy, to have the previously described pig-tail, arcuate shape described in FIGS 8, 9, and 10. The transition temperature of the shape memory material should be chosen to be close to normal 30 body temperature so that extreme temperature variations to achieve malleability or to recall the stored shape will not be necessary for the respective retraction or deployment of the elements

5 formed from the material. The shape memory material of the wire elements should be annealed in the deployed position to confer a shape memory in this configuration. Then, the wire elements should be cooled below the transition temperature of the shape memory material, so that the wire support structure is malleable and can be shaped into a collapsed position. Depending on the transition temperature, this can preferably be done at room temperature or in iced saline solution. The bumper elements 1270 having the integral wire elements can be retracted into the tube device 1215 to facilitate instrument insertion and to avoid premature deployment of the bumpers.

10 Once the instrument is in position within the patient's blood vessel, the bumper elements 1270 are deployed and heated above the transition temperature so the wire elements recall their stored shape. Depending on the transition temperature of the shape memory material, the bumper structure can be passively heated by body heat (accounting, of course, for decreased body 15 temperature during hypothermic cardiopulmonary support methods) or it can be self-heated by applying an electrical current through the bumper wire element structure. When heated, the bumper elements 1275 expand to their annealed configuration within the blood vessel. After use, the bumper is returned to the collapsed position by retraction into the tube device of the instrument. This optional adaptation, for incorporating preshaped wire elements, is contemplated for all embodiments and variations of the present invention.

20 In addition, as shown in FIG 10, the instrument 1210 is also formed with a bumper element actuator 1275 adapted to independently or simultaneously deploy and retract the corresponding bumper element(s) 1270. The bumper elements 1270 are typically positioned in a retracted configuration within the shaft 1270 to facilitate insertion and removal of the instrument 1210 into and from the patient's ascending aorta 35. Once the distal end 1260 is 25 inside the ascending aorta and has been advanced near the selected location, the bumper device 1265 is deployed by sliding the pigtail catheters out of the shaft 1215. The elements 1270 will then assume the pig-tail, arcuate configuration as they advance out of the shaft, forming a generally curved distal end for bumping against or engaging either the aortic valve annulus 39, the walls of the aortic sinuses at the aortic root 38, the individual corresponding leaflets 44, 30 and/or the sinotubular ridge of the natural or prosthetic aortic valve 42.

The actuators 1275 are adapted to deploy and retract the preshaped bumper elements or pushers 1275 which are formed as arcuate spring members, or wire frame pushers, from a material having the elastic, superelastic or shape memory characteristics described above, so that, when deployed, elements 1275 generally conform to the shape of the aortic valve leaflets 44.

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FIG 11 depicts another embodiment 1310 of a bumper device 1365 having coiled wire or plastic filament filled, permeable-membrane-type bumper elements 1370. The permeable membrane of this illustrative embodiment prevents the bumper elements 1370 from blocking the ostia of the coronary arteries 36 as the instrument 1310 is advanced or retracted from the selected location past the ostia. This embodiment is also compatible for use as a weeping bumper mechanism operative to perfuse a fluid at precalibrated flow rates through the permeable membrane in a similar manner as described above for the weeping CPFR. Further, even though a CPFR is not shown in these figures, its optional incorporation in this embodiment is contemplated and can be understood from the descriptions of the previous illustrative embodiments. In operation, the CPFR deployed above the coronary ostia creates an isolated chamber in the lumen of the aortic sinus region 38 whereby a lumen of the instrument 1310 is in fluid communication with the coronary arteries. The bumper mechanism 1365 further incorporates an impermeable lower surface formed on each lobe 1370 which prevents regurgitant fluid flow across the aortic valve while the upper surface is formed with the weeping, permeable membrane. While the isolated chamber is perfused by the weeping bumper elements 1370, an additional fluid communication lumen connected to an additional port 1355 may be incorporated in a further variation of this embodiment for perfusion, irrigation, aspiration or for pressure sensing, among other uses.

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An additional embodiment is shown in FIG 12 that is similar to that of FIG 11. However, the bumper device 1465 of this embodiment incorporates bumper elements 1470 having a preformed, perforate, skinless foam construction, which may or may not further include a wire-frame or wire mesh-type endoskeleton supporting the foam. As with the configuration of FIG 11, this design prevents blockage of the coronary ostia 36 as the bumper elements 1470 are advanced or retracted from the selected location and allows weeping bumper perfusion as previously described.

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In the embodiments illustrated by FIGS 10 and 11, the respective bumper mechanisms may be partially moved away from the aortic valve in an antegrade direction to allow normal operation of the valve, while the heart is ejecting, without blocking the coronary ostia. Thus, the instruments of these embodiments may continue to perfuse, irrigate, aspirate or sense pressure without affecting normal valve function or blood flow to the coronary arterial bed. This configuration can be especially useful when the patient is to be weaned from cardiopulmonary bypass and before it is deemed safe to completely remove the coronary isolator catheterization and bumper instrument.

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FIGS 13, 14, 15 and 16 depict side views of alternative embodiments of the CPFR discussed above. In these embodiments, the aortic catheterization instrument is shown generally by reference numeral 1510 and includes a CPFR operative in response to fluid flow thereby to function as a one way check valve to allow flow in one direction while simultaneously preventing fluid flow in the opposite direction. The CPFR of the previous embodiments has been replaced by the umbrella-shaped CPFR 1580 shown in cross-section in each of the figures. FIG 13 shows the CPFR 1580 mounted to the tube device shaft 1515 and positioned in the aortic lumen 35 proximate to the selected location discussed above. The fluid flow directional arrows of FIG 13 reflect normal antegrade flow past the valve. The CPFR 1580 may be remotely retracted from the external location 25 with optional actuators 1585. The actuators 1585 may be configured to limit the retrograde deflection of the CPFR 1580 to prevent deformation in the retrograde direction or may limit the deflection so as to enable a predetermined retrograde rate of fluid flow past the CPFR 1580. This is accomplished by the actuators 1585 operating to limit the CPFR from extending, in response to retrograde fluid flow, to its fully deployed configuration. In operation, the CPFR 1580 does not restrict the flow of fluid from the aortic root side 1538' in the downstream, antegrade direction. However, as shown in FIG 14, retrograde, upstream flow, depicted by the fluid flow directional arrows, engages the CPFR 1580 and thereby passively deploys it into a fluid blocking relationship with the walls of the aortic lumen 35 as shown in FIGS 15 and 16. The pressure differential between the upstream or aortic root side 1538' and the downstream or aortic arch side 1538'' of the CPFR 1580 is maintained during surgical interventions when the patient is placed on cardiopulmonary bypass. Typically,

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when a patient is placed on cardiopulmonary bypass, a mixture of temperature controlled fluids and blood is pumped into the patient's aorta downstream 1538" of the CPFR 1580 at a rate of flow sufficient to create the above-described retrograde flow which engages the CPFR. The CPFR may also be deployed by application of a vacuum to the upstream or aortic root side 1538' of the CPFR 1580. This pressure differential is also maintained even with perfusion of fluids to the upstream side 1538' so long as the fluid perfusion pressure does not exceed the cardiopulmonary bypass perfusion pressure at the downstream side 1538" of the CPFR 1580.

As with the CPFR's of previous embodiments, the CPFR 1580 is mounted symmetrically about the tube device shaft 1515 such that when the CPFR deploys, it radially centers the distal end 1560 in the aortic lumen 35. Additionally, the surface of the CPFR 1580 which contacts the walls of the aortic lumen 35 may be specially shaped or coated to atraumatically engage the intimal blood vessel walls when deployed to prevent longitudinal displacement or movement of the instrument 1515 while the fluid pressure differential is maintained. Additional variations to this embodiment may be incorporated wherein the CPFR is formed with or reinforced with preshaped materials having shape memory as described above which actively extends the CPFR into the blood vessel lumen as the CPFR actuators are manipulated or as the CPFR is otherwise deployed. Although the exemplary CPFR embodiment described here is generally disposed in a fixed position relative to a distal end of the instrument 1510, alternative embodiments may be adapted to incorporate a longitudinally repositionable CPFR analogous in operation to the previously described repositionable CPFR embodiments.

The CPFR of this embodiment may also be configured in alternative variations to incorporate the blood vessel lumen flow regulating elements described in copending, commonly owned application serial no. 08/664,361 filed on June 17, 1996 which is hereby incorporated by reference in its entirety.

Referring now to FIGS 17 and 18, another alternative embodiment 1600 of the present invention is shown which incorporates a modified CPFR and bumper arrangement. The catheter position and stabilization engagement functions are achieved by a toroid-shaped inflatable balloon 1602 while the flow regulation is accomplished by a poppet valve and seat assembly

1605 disposed in a poppet cage formed from extendible bumper wires 1608 when in the deployed position. The wires are preferably formed from a shape memory capable material as described above. The toroid-shaped balloon 1602, wires 1608 and the seat 1612 are configured to be 5 retractably deployed from an annular concentrically disposed space 1615 formed in the distal end of the instrument 1600. The tubular interior wall 1616 of the annular space surrounds one or more fluid communication lumens, one of which is in communication with port 1614. This interior wall 1616 extends distally from the space 1625 below the seat 1610. The poppet 1612 is captivated in the bumper cage about the exterior of the tubular wall 1616 and slides passively up and down in response to fluid flow in the blood vessel lumen. The poppet 1612 is formed as 10 either an inflatable disc-shaped member or as a flexible disc having a shape memory such that, when deployed, it unfurls to assume the configuration and/or orientation shown.

One exemplary embodiment of the poppet includes a flexible disc of material formed with either integral radially disposed stiffening ribs or a spiral shape memory metal skeleton, either of which forces the poppet to unfurl upon deployment and which refurls the poppet into a lumen or passageway of the instrument upon retraction. Each of the following embodiments which incorporate the poppet configuration is intended to incorporate some aspect of this poppet configuration. A variation of this embodiment includes an actuator connected to the poppet and extending to an external location for active actuation of the poppet valve assembly.

20 The poppet 1610 and seat 1612 combination are shown in the closed position in FIG 17 which prevents retrograde, upstream flow of fluid from the ascending aorta to the aortic root 38. This closed position is maintained while the pressure of fluid downstream of the poppet 1610 is greater than the pressure of fluid upstream of the poppet 1610 such as when the aortic arch is 25 pressurized with oxygenated blood while the patient is on cardiopulmonary bypass. FIG 18 reflects the position of the poppet 1610 relative to the seat 1612 when the pressure downstream falls below the pressure upstream of the poppet 1610 such as when the distal port 1614 of the bumper instrument is used to perfuse additional bypass blood flow for, perhaps, rapid rewarming of a patient who is to be resuscitated from cardiac arrest and weaned from cardiopulmonary bypass. Also shown in both FIGS 17 and 18 is a venting, pigtail-type catheter 1618 which has 30 been described above in connection with previously described embodiments. Each of the

elements, configurations and variations of this embodiment are compatible for incorporation with the previously and later described embodiments as well as in any number of possible combinations.

5 FIGS 19 and 20 reflect an additional CPFR and bumper embodiment 1650 similar to that shown in FIGS 17 and 18 except that the poppet 1660 and seat 1662 are configured to control and prevent fluid flow in the direction opposite to that shown in FIGS 17 and 18. The poppet closes as shown in FIG 20 in response to antegrade fluid flow such as when pressurized cardioplegia is to be perfused to the coronary arteries in an antegrade direction from the distal 10 port of the bumper instrument or retrograde through the coronary arterial bed from the coronary sinus. Additionally, the toroidal catheter position stabilizer has been replaced with the inflatable balloon 1655 of earlier embodiments. Both the poppet 1660 and seat 1662 as well as the inflatable balloon may operate as flow regulators in this embodiment as can be understood from this and previously described embodiments.

15 The next CPFR and bumper embodiment 1670 illustrated in FIGS 21 and 22 incorporates a toroidal catheter position stabilizer 1672 similar in construction to that of FIGS 17 and 18 along with a poppet 1674 operative, as in FIGS 19 and 20, to prevent antegrade flow. However, here the catheter position stabilizer 1672 operates as the poppet seat of previous embodiments to prevent 20 downstream antegrade fluid flow.

25 In FIGS 23 and 24, an alternative embodiment 1680 to the CPFR and bumper shown in FIGS 21 and 22 accommodates advancement of a venting catheter 1682, as described previously, past the poppet 1684, past the aortic valve leaflets 44 and into the left ventricle. The vent catheter 1682 may be integrally formed with the bumper instrument 1680 to be fixed in position relative to the distal end of the instrument shaft or may be extendible and retractable to be advanced past the aortic valve 42 and into the left ventricle. The poppet 1684 is free to slide along the shaft of the vent catheter 1682, within the confines of the poppet cage formed by the wire bumper elements 1686, in response to upstream and downstream pressure changes. In a 30 further variation of this embodiment, the poppet 1684 may be mounted to the exterior of the vent

catheter shaft 1682 such that flow past the poppet-stabilizer flow regulator can be remotely actuated from the external location by extension and retraction of the vent catheter 1682 a predetermined distance. Wire bumper members 1698 are shown in a deployed position and biased downwardly against the corresponding aortic valve leaflets 44.

5 Similar in construction to the embodiment 1680 described by FIGS 23 and 24, another CPFR and bumper instrument embodiment 1690 is shown in the perspective view of FIGS 25 and 26 which incorporate an actuator 1692 connected at a distal end to a poppet or valve member 1694 and extending to an external location. In this configuration, the poppet 1694 may be positively actuated remotely at the external location to control the flow in the aortic lumen. To 10 stop the flow of blood and/or fluid through the instrument 1690, the poppet 1694 is actuated from an open position as shown in FIG 25 to a closed position by actuation in the downstream direction away from the aortic valve to sealingly seat against a toroidally shaped inflatable CPFR 1696 as can be understood from FIG 26. In FIG 27, a variation of this embodiment is indicated 15 generally by reference numeral 1690' with a poppet 1694' repositioned to be actuatable to push against wire bumper members 1698' which, in turn, push against the aortic valve leaflets 44 thereby biasing the leaflets 44 in a more closed position and preventing transvalvular fluid regurgitation. The closed position is reflected by FIG 28.

Another variation of the bumper instrument embodiments 1690 and 1690' are shown in FIGS 29 and 30. In FIG 29, the bumper instrument 1700 is shown without a CPFR and is compatible for use with an aortic cross clamp such as that described with respect to FIG 2 above. Nevertheless, this particular embodiment may also include the CPFR's of previous embodiments. This variation reflects the same operative configuration of FIGS 26 and 27 as viewed from a side perspective in FIG 29, showing a poppet 1704 in the open position and bumper wire pusher members 1708 biased against the valve leaflets 44. In this variation, the pushers 1708 are shaped 20 to allow partial antegrade flow where the heart is still partially ejecting. However, the poppet 1704 is formed of a material rigid enough to push against the pushers 1708 while being flexible enough for withdrawal through the catheter lumen of the instrument 1700. The poppet 1704 may 25 be deployed downwardly by manipulation of an actuator 1702 to push against the pushers 1708

which, in turn, push against and bias the valve leaflets in a more closed position to prevent regurgitant fluid flow into the left ventricle.

In FIGS 31 and 32, another variation of the bumper instrument is shown generally by reference numeral 1720 in which manipulation of actuator 1722 deploys or retracts a poppet 1724. When deployed as shown in FIG 32, the poppet 1724 is adapted to push directly against the upper edge of the valve leaflets 44 at the commissures to bias the valve in a more closed position to prevent regurgitant fluid flow. The bumper wire pusher members are configured to rest against the lowermost portion of the cusps of the leaflets 44. As can be understood from FIG 32, the poppet 1724 is formed from a material which is deformable to atraumatically push against the valve commissures.

FIGS 33 and 34 reflect an additional embodiment of a bumper and CPFR instrument 1740 which is formed as an inflatable balloon having the shape of an hour glass with upper 1742 and lower 1744 portions. The upper portion CPFR 1742 is preshaped and sized to sealingly but atraumatically engage the walls 35 of the aortic lumen. The lower portion bumper 1744 is shaped to correspondingly engage with and bump against the respective cusps of the aortic valve leaflets such that the leaflets will be biased in a more closed position. In one variation of the lower portion, it is formed to have three lobes to correspond with the most common anatomical configuration of the aortic valve leaflets 44. In another variation, the lower portion is formed to bump against and engage the aortic sinus regions or to be sized, when inflated, to engage the aortic annulus 39 for longitudinal position stabilization of the instrument 1740. Additionally, the upper portion 1744 may be configured, when inflated, to engage the sinotubular ridge. At least one fluid communication port 1746 is disposed about the waist or narrow portion 1745 of the hour glass CPFR 1742 and bumper 1744 to perfuse or aspirate fluids to the coronary ostia. The size and shape of the upper and lower portions are preconfigured to, when fully inflated, prevent obturation of the coronary ostia. Also, the instrument 1740 may be configured with additional inflation lumens so that the upper CPFR and lower bumper portions of the instrument may be independently inflatable. In either variation of this embodiment, the upper CPFR portion may be partially inflated so as to regulate fluid flow thereby. The instrument 1740 of this embodiment may also be configured with a transvalvular pigtail type fluid communication

catheter 1748 for aspirating, irrigating or perfusing fluids to and from the left ventricle. The catheter 1748 may either be integrally formed or may be introduced through a lumen of the catheter 1748. Other instruments, devices or catheters may be similarly introduced into the heart chambers.

5 Another embodiment of the CPFR, bumper instrument of the present invention is indicated generally by reference numeral 1760 in FIGS 35 and 36 having a similar, hour glass type configuration as the previous embodiment. An independently inflatable CPFR 1762 and bumper 1764 are depicted with a fluid communication port 1766 formed in the catheter shaft therebetween. The bumper or poppet member 1764 is formed to be generally planar and is sized to push against, when deployed against the commissures of aortic valve leaflets 44, and bias the leaflets 44 in a more closed position to prevent regurgitant fluid flow. The CPFR 1762 may be fully inflated to sealingly engage the aortic lumen walls or partially inflated to regulate fluid flow. When both the CPFR 1764 and the poppet bumper 1764 are fully inflated, they cooperate to form an isolated chamber which is in fluid communication with the coronary ostia. As 10 described before, a transvalvular pigtail catheter or other device may be incorporated with this 15 embodiment.

Introduction via other leg, arm, neck and corporeal blood vessels, including the axillary, 20 subclavian or carotid arteries, would establish other preferred preshaped shaft configurations and embodiments. Referring now to FIG 37, another exemplary embodiment of the invention 3710 is shown with of the instrument shaft 3715 introduced through a peripheral vessel, such as the femoral artery. Preferably, the shaft 3715 would be formed to have a generally "U"-shaped, 25 partial spiral configuration to follow, in the upstream, retrograde direction, the three dimensional contour of the centerline of the descending aorta, upstream through the arch and finally downward through the ascending aorta towards the aortic root 38. In this embodiment the device is shown with only the bumper instrument 3765, and a pigtail-type venting device slidable through the common lumen 3795.

To more fully understand the composition of the bumper instrument 3765 a schematic of the bumper is provided in FIGS 39 and 40. FIG 39 depicts the bumper instrument

as viewed from either the top or bottom. The bumper elements 3770 are similar in shape and size to that of the FIG 1 bumper element(s) 70, however in the present embodiment a common web-like membrane 3777 connects the bumper elements. In this particular embodiment of the bumper device adjustment of the device after deployment is made easier due to the communication of all the bumper elements. This adjustment provides for optimum contact with the aortic root valve in order to render the valve competent. In addition it is understood that in the case of abnormal root valves the bumper elements may be only two. The bumper 3765 may be formed by heat sealing or adhesively bonding two sheets of plastic material in a pattern to create the web 3777 and the bumper elements 3770.

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FIG 40 is a lateral view of FIG 39 and shows the shaft 4015 as it extends through the bumper device 3765. Again, it should be understood that the shaft may extend therethrough in order to facilitate the use of additional catheters such as a pigtail-type venting device. When circumstances warrant, the bumper device may constitute the most proximal portion of the bumper instrument 4010 for tactile feedback.

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Referring now to FIG 38, there is represented another embodiment of the present device. Again, in this example, the device is being depicted as being used for the femoral approach. The bumper instrument is similar to that of FIG 37 except there is a CPFR 3880 placed and inflated in the ascending aorta and another CPFR 3880 placed and inflated in the descending aorta. Both CPFR's are depicted as balloons, however it is understood that the CPFR could be any number of the above described regulators. In addition, shaft 3815 has an additional perfusion lumen 3820 and perfusion ports 3830 capable of perfusing the arch and corporeal circulation separately and independently due to the segmentation of the aortic vessel by the CPFR's. The bumper device 3870 in this embodiment is the same as that depicted in FIGS 39 and 40 and is shown with the use of a secondary pigtail-type venting device 3895. Segmentation and differential perfusion of the aorta are described in more detail in U.S. Patents 5,308,320 and 5,383,854 and in commonly owned, copending U.S. Provisional Patent applications 60/067,945, filed December 8, 1997, and 60/084,835, filed May 8, 1998, the specifications of which are hereby incorporated in their entirety.

5 FIG 41 is another exemplary embodiment of the described invention where the elongated shaft of the tube device 4115 is introduced specifically through the subclavian artery. In this particular embodiment there is an attached catheter position stabilizer-flow regulator 4180 proximal to the bumper device. In addition the bumper elements in this embodiment are connected by the common web-like attachment to better facilitate adjustment to the aortic leaflets as depicted in FIGS 39 and 40. The device has corresponding diametrical and length dimensions preshaped and sized to correspond with the various anatomical geometries of other selected peripheral or central blood vessels and is capable of perfusing the arch vessels through the perfusion port 3830 in communication with perfusion lumen 3820.

10 FIG 42 is another exemplary embodiment of the described invention where the elongated shaft of the tube device 4215 is introduced specifically through the subclavian artery. In this particular embodiment there is an attached CPFR 4280 proximal to the bumper device which is in the form of a valve that allows for greater flow in the antegrade direction than in the retrograde direction. In addition the bumper elements in this embodiment are connected by the common web-like attachment to better facilitate adjustment to the aortic leaflets as depicted in FIGS 39 and 40. The device has corresponding diametrical and length dimensions preshaped and sized to correspond with the various anatomical geometries of other selected peripheral or central blood vessels and is capable of perfusing the arch vessels through the perfusion port 3830 in communication with perfusion lumen 3820.

15 20 In either the femoral approach or the subclavian approach, the instrument is compatible with both minimally invasive closed-chest, endovascular and open-chest surgical interventions.

25 30 Each of the described embodiments may also be adapted to have a construction similar to the weeping type balloon CPFR or weeping bumper components described above. In such variations, the poppet or bumper members are deployed or inflated and then positioned to rest against the aortic valve 42 to prevent transvalvular regurgitation while simultaneously perfusing a fluid at a precalibrated flow rate to the aortic root and the coronary arteries. As with earlier embodiments, the poppet or bumper member is formed with an impermeable lower surface which sealingly rests against the aortic valve and an upper permeable surface with a membrane material or pattern of micro-perforations in the material which have or establish a predetermined porosity

with respect to a particular perfusate composition at a particular temperature. The bumper or poppet member may be fabricated from any number of suitable materials including, but not limited to, an open-cell foam or a micro-perforated inflatable balloon material similar in construction to previously described embodiments.

5 Referring now to figure 43 the catheter instrument has positioned at the distal end 60 a bumper mechanism or device 4365 with multiple retractable bumper elements 4370. The bumper elements 4370 are pre-shaped, pigtail-type perfusion and venting catheters, and in the preferred embodiment there are three such catheters slidably disposed within the shaft 4315 to correspond to the three aortic valve leaflets encountered in most patients. However, some patients may have 10 an aortic valve with either one or more valve leaflets while others may have a valve prosthesis implanted and in such patients, the bumper 4365 may need to be configured according to the particular patient's native anatomical or prosthetic valve configuration so as to prevent damage to the valve or the aortic root and also to ensure compatibility of the instrument with the particular configuration of the valve and aortic root.

15 For example, the bumper device may be configured with a single bumper element 4370 which is adapted to correspond with a single leaflet anatomical variant of the more common three leaflet heart valve. In a more preferable embodiment, bumper 4365 is configured with independently actuatable bumper elements 4370. This embodiment may incorporate two or more bumper elements 4370 such that one, two, three or more elements 4370 may be deployed, 20 corresponding with the number of native or prosthetic valve leaflets, to bump against such leaflets for purposes described in detail below. The independent operability of this alternative embodiment renders it compatible for use with a variety of differently configured native and prosthetic valve configurations. Thus, the need for bumper instruments custom adapted for use 25 with a particular single or double atypical anatomical valve configuration may, in some cases, be eliminated.

30 In any variation of various embodiments, the outer circumferential diameter of the deployed bumper 4365 is preferably sized to engage anatomical aortic structures having average internal, cross-sectional diameters approximately in the range of 1-5 centimeters in diameter and

more preferably approximately in the range of 2-3 centimeters, to accommodate the normal human adult range of internal aortic luminal, root, annulus and sinotubular ridge diameters. Smaller and larger diameters are indicated for pediatric patients and for very large patients, respectively.

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The bumper elements 70 of the exemplary embodiment are fabricated from the same or similar materials described above for the elongated tube device shaft 4315. Such elements 4370 are pre-shaped to have the desired pig-tail, arcuate shape as shown in FIGS 43 and 44 and are fabricated to have sufficient shape memory and rigidity to, when deployed, bump against the aortic valve leaflets 44. Further, the bumper elements 4370 are also fabricated to have enough flexibility to, when fully retracted within tube device 4315 assume a substantially straightened orientation for introduction to and removal from the patient's blood vessel.

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Although not shown in the figures, the precision engineered aortic catheterization bumper instrument of the invention may also be modified to incorporate various types of filters for filtering embolic material from the flow of fluid and blood in the aortic lumen and thereby reduce the incidence of cerebral or cardioneural complications generally associated with the release of atheromatous or calcific embolic debris resulting from aortic cross-clamping or the inflation of an aortic occlusion balloon and which is dispersed into the neurovasculature. Another filter configuration not shown in the figures but contemplated by the invention includes a windsock-type filter mounted on the instrument which is porous to blood but impermeable to particulate emboli and which includes an emboli aspiration lumen at the apex of the windsock. Such filters may also be used adjunctively as a separate instrument or device as described in copending, commonly owned U.S. Provisional Patent Application serial no. 06/060,117 filed on September 26, 1997 which, together with its corresponding utility patent application, is hereby incorporated by reference in its entirety.

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While the present invention has been described herein with respect to the exemplary embodiments and the best mode for practicing the invention, it will be apparent to one of ordinary skill in the art that many modifications, improvements and subcombinations of the

various embodiments, adaptations and variations can be made to the invention without departing from the spirit and scope thereof; the invention being defined by the claims.

WHAT IS CLAIMED IS:

1. An aortic catheter, comprising:
an elongated catheter shaft having a proximal end and a distal end; and
a bumper device positioned proximate said distal end of said elongated catheter
shaft and configured for contacting a patient's aortic valve and biasing the aortic valve toward
a closed position.
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2. The aortic catheter of claim 1, wherein said bumper device comprises at least one
bumper element configured to conform to at least one valve leaflet of the aortic valve.
3. The aortic catheter of claim 1, wherein said bumper device comprises three
bumper elements configured to conform to three valve leaflets of the aortic valve.
4. The aortic catheter of claim 1, wherein said bumper device comprises a single
bumper element configured to conform to three valve leaflets of the aortic valve.
5. The aortic catheter of claim 1, wherein said bumper device comprises at least one
inflatable bumper element.
6. The aortic catheter of claim 1, wherein said bumper device comprises three
inflatable bumper elements.
7. The aortic catheter of claim 1, wherein said bumper device comprises a single
inflatable bumper element configured to conform to three valve leaflets of the aortic valve.
8. The aortic catheter of claim 1, wherein said bumper device comprises a wire-
frame skeleton.
9. The aortic catheter of claim 8, wherein said bumper device further comprises a
bumper skin covering said wire-frame skeleton.

10. The aortic catheter of claim 1, wherein said bumper device is at least partially porous.

11. The aortic catheter of claim 1, wherein said bumper device comprises three extendible wire bumper elements.

12. The aortic catheter of claim 11, wherein said three extendible wire bumper elements are configured to conform to three valve leaflets of the aortic valve.

13. The aortic catheter of claim 1, wherein said bumper device comprises a plurality of bumper elements having a web connecting adjacent bumper elements.

14. The aortic catheter of claim 1, wherein said bumper device comprises three inflatable bumper elements having a web connecting adjacent bumper elements.

15. The aortic catheter of claim 1, further comprising a catheter position stabilizer flow regulator mounted on said elongated catheter shaft.

16. The aortic catheter of claim 15, wherein said catheter position stabilizer flow regulator comprises an inflatable occlusion balloon.

17. The aortic catheter of claim 15, wherein said catheter position stabilizer flow regulator comprises an external catheter flow regulating valve.

18. The aortic catheter of claim 15, further comprising a second catheter position stabilizer flow regulator mounted on said elongated catheter shaft.

19. The aortic catheter of claim 1, further comprising a poppet valve mounted on said elongated catheter shaft.

20. The aortic catheter of claim 1, wherein said elongated catheter shaft comprises at least one fluid flow lumen extending therethrough.

21. The aortic catheter of claim 20, wherein said elongated catheter shaft further comprises a second fluid flow lumen extending therethrough.

22. The aortic catheter of claim 1, wherein said elongated catheter shaft comprises at least one torque transmitting member therein.

23. The aortic catheter of claim 1, wherein said torque transmitting member comprises a torque catheter shaft.

24. The aortic catheter of claim 1, further comprising a venting catheter member configured for crossing the patient's aortic valve and venting the patient's left ventricle.

25. An aortic catheter, comprising:

an elongated catheter shaft having a proximal end and a distal end; and

5 a bumper device positioned proximate said distal end of said elongated catheter shaft, said bumper device having a plurality of bumper elements configured for contacting a plurality of valve leaflets of a patient's aortic valve.

26. The aortic catheter of claim 25, wherein said bumper device is configured for biasing the aortic valve toward a closed position.

27. The aortic catheter of claim 25, wherein said bumper device comprises three bumper elements configured for contacting three leaflets of the aortic valve.

28. The aortic catheter of claim 25, wherein said bumper device comprises three bumper elements configured to conform to three valve leaflets of the aortic valve.

29. The aortic catheter of claim 25, wherein said bumper device comprises at least one inflatable bumper element.

30. The aortic catheter of claim 25, wherein said bumper device comprises three inflatable bumper elements.

31. The aortic catheter of claim 25, wherein said bumper device comprises a wire-frame skeleton.

32. The aortic catheter of claim 31, wherein said bumper device further comprises a bumper skin covering said wire-frame skeleton.

33. The aortic catheter of claim 25, wherein said bumper device is at least partially porous.

34. The aortic catheter of claim 25, wherein said bumper device comprises three extendible wire bumper elements.

35. The aortic catheter of claim 34, wherein said three extendible wire bumper elements are configured to conform to three valve leaflets of the aortic valve.

36. The aortic catheter of claim 25, wherein said bumper device comprises a web connecting adjacent bumper elements.

37. The aortic catheter of claim 25, wherein said bumper device comprises three inflatable bumper elements having a web connecting adjacent bumper elements.

38. The aortic catheter of claim 25, further comprising a catheter position stabilizer flow regulator mounted on said elongated catheter shaft.

39. The aortic catheter of claim 38, wherein said catheter position stabilizer flow regulator comprises an inflatable occlusion balloon.

40. The aortic catheter of claim 38, wherein said catheter position stabilizer flow regulator comprises an external catheter flow regulating valve.

41. The aortic catheter of claim 38, further comprising a second catheter position stabilizer flow regulator mounted on said elongated catheter shaft.

42. The aortic catheter of claim 25, further comprising a poppet valve mounted on said elongated catheter shaft.

43. The aortic catheter of claim 25, wherein said elongated catheter shaft comprises at least one fluid flow lumen extending therethrough.

44. The aortic catheter of claim 43, wherein said elongated catheter shaft further comprises a second fluid flow lumen extending therethrough.

45. The aortic catheter of claim 25, wherein said elongated catheter shaft comprises at least one torque transmitting member therein.

46. The aortic catheter of claim 25, wherein said torque transmitting member comprises a torque catheter shaft.

47. The aortic catheter of claim 25, further comprising a venting catheter member configured for crossing the patient's aortic valve and venting the patient's left ventricle.

48. An aortic catheter, comprising:
an elongated catheter shaft having a proximal end and a distal end; and

5 a bumper device positioned proximate said distal end of said elongated catheter shaft and an actuator member for deploying said bumper device into a configuration for contacting a patient's aortic valve.

49. The aortic catheter of claim 48, wherein said bumper device is configured for biasing the aortic valve toward a closed position.

50. The aortic catheter of claim 48, wherein said actuator member comprises at least one elongated pusher member for urging at least one bumper element into contact with the aortic valve.

51. The aortic catheter of claim 50, wherein said at least one bumper element comprises at least one inflatable bumper element.

52. The aortic catheter of claim 51, wherein said at least one bumper element comprises three inflatable bumper elements

53. The aortic catheter of claim 48, wherein said actuator member deploys said bumper device to expand outward.

54. The aortic catheter of claim 48, wherein said actuator member comprises an expandable wire-frame skeleton.

55. The aortic catheter of claim 54, wherein said bumper device comprises a bumper skin covering said wire-frame skeleton.

56. The aortic catheter of claim 55, wherein said bumper skin covering said wire-frame skeleton is at least partially porous.

57. The aortic catheter of claim 48, wherein said bumper device comprises three extendible wire bumper elements configured to contact three valve leaflets of the aortic valve.

58. The aortic catheter of claim 48, wherein said elongated catheter shaft comprises at least one lumen and wherein said actuator member deploys said bumper device from a collapsed position within said lumen.

59. An aortic catheter, comprising:

an elongated catheter shaft having a proximal end and a distal end; and
a bumper device positioned proximate said distal end of said elongated catheter shaft, said bumper device having a distal surface with three lobes configured to conform to three valve leaflets of the aortic valve.

60. The aortic catheter of claim 59, wherein said bumper device is configured for biasing the aortic valve toward a closed position.

61. The aortic catheter of claim 59, wherein said bumper device comprises at least one inflatable bumper element.

62. The aortic catheter of claim 59, wherein said bumper device comprises an expandable wire-frame skeleton.

63. The aortic catheter of claim 62, wherein said bumper device further comprises a bumper skin covering said wire-frame skeleton.

64. The aortic catheter of claim 63, wherein said bumper skin covering said wire-frame skeleton is at least partially porous.

65. A method of aortic catheterization, comprising:
introducing a distal end of an aortic catheter into a patient's aorta;
advancing said aortic catheter until a bumper element mounted proximate said distal end of said aortic catheter contacts the patient's aortic valve; and
urging the aortic valve toward a closed position with said bumper element.

66. The method of claim 65, further comprising:
deploying said bumper element from a collapsed position.

67. The method of claim 66, wherein said bumper element is deployed from within
a lumen in said aortic catheter.

68. The method of claim 66, wherein said bumper element is deployed by inflating
said bumper element.

69. The method of claim 66, wherein said bumper element contacts three valve
leaflets of the patient's aortic valve.

70. The method of claim 65, further comprising:
occluding a lumen of the patient's aorta downstream of the patient's aortic valve.

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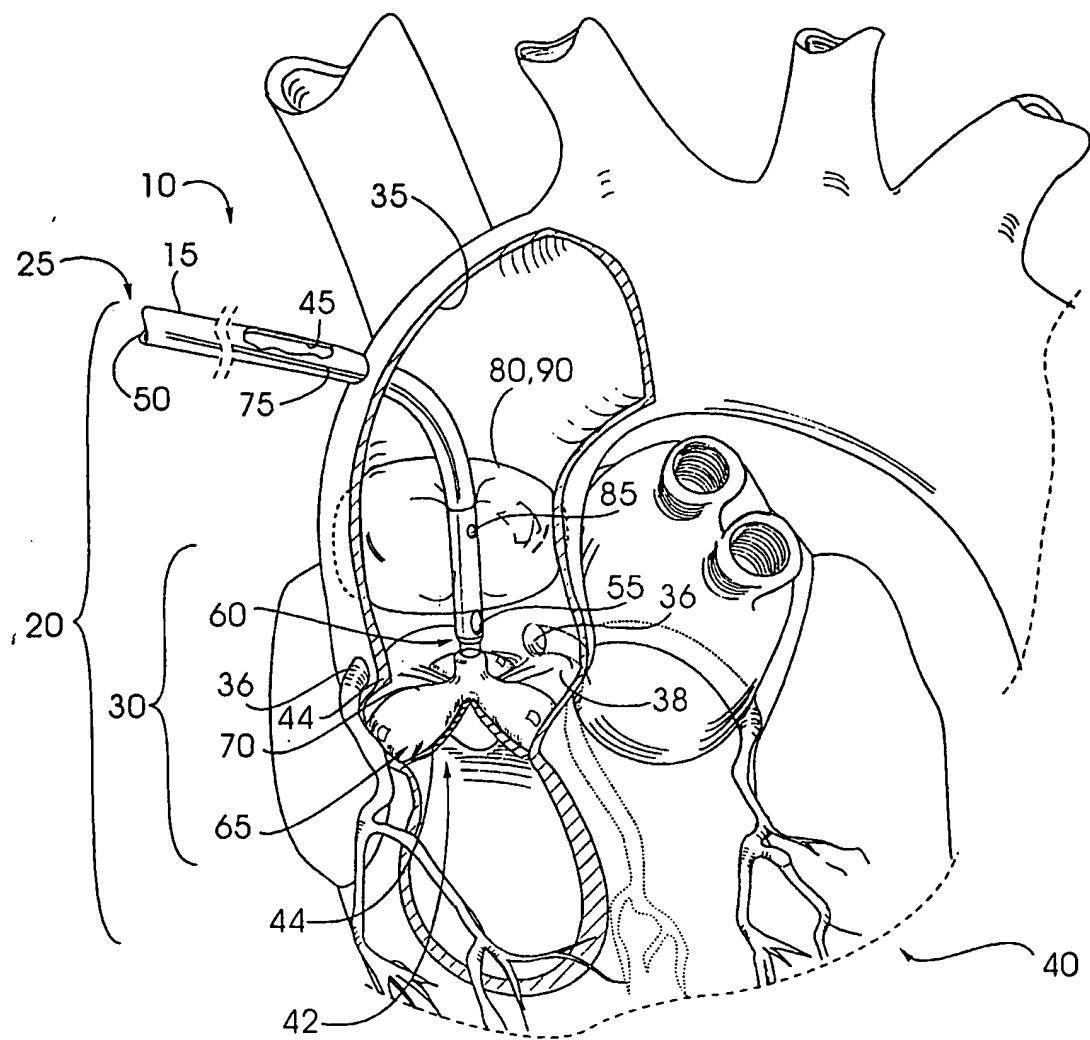


FIG 1

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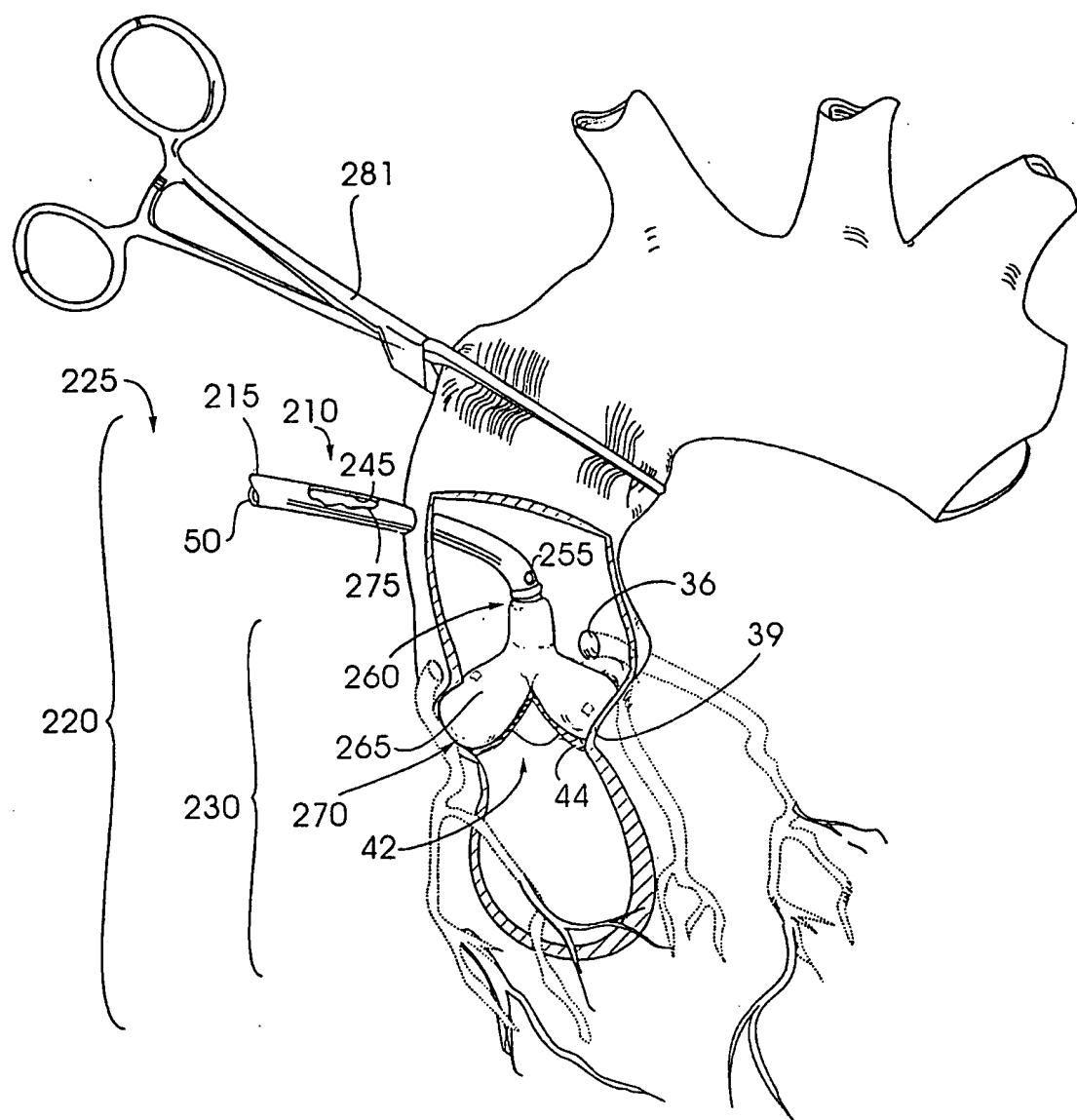
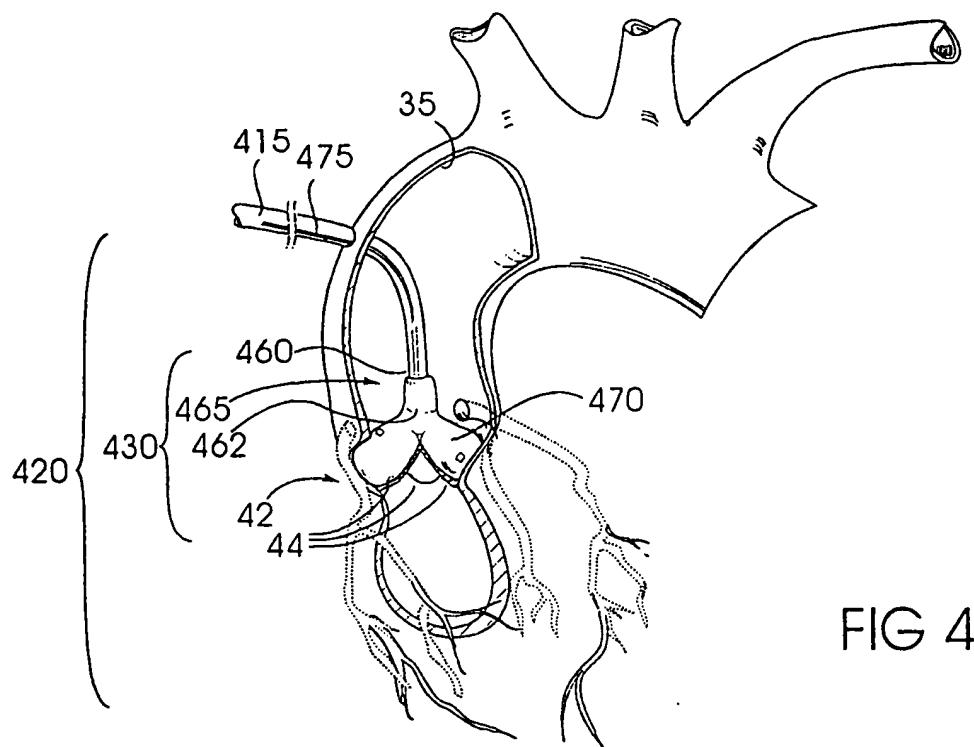
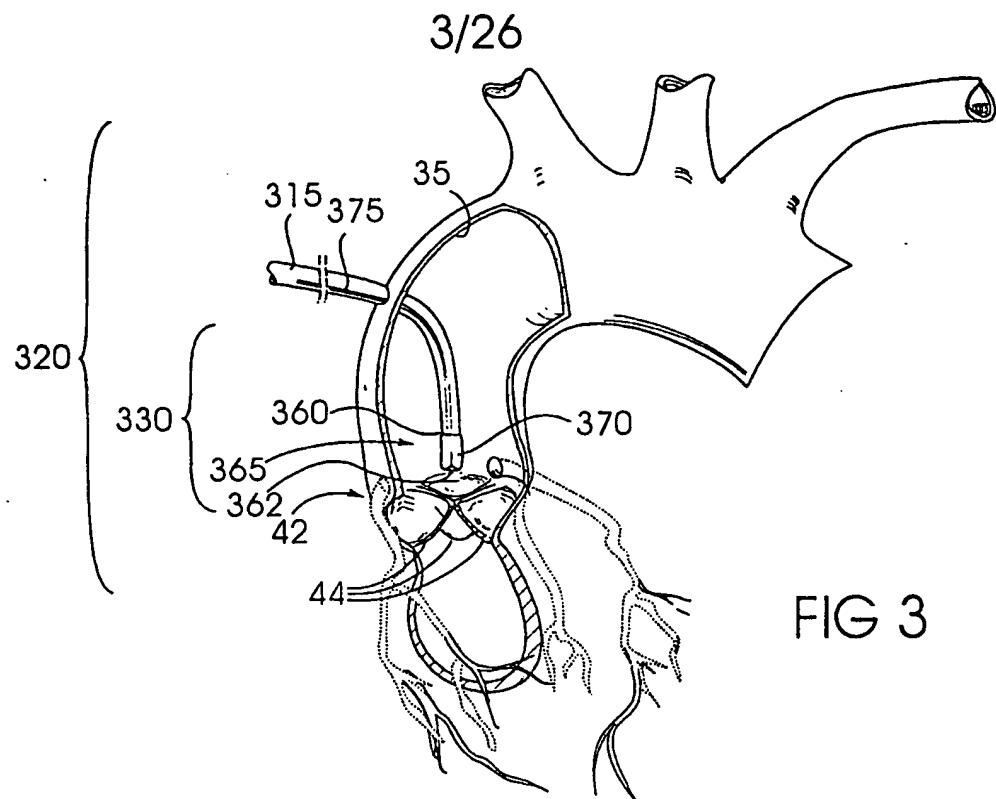


FIG 2



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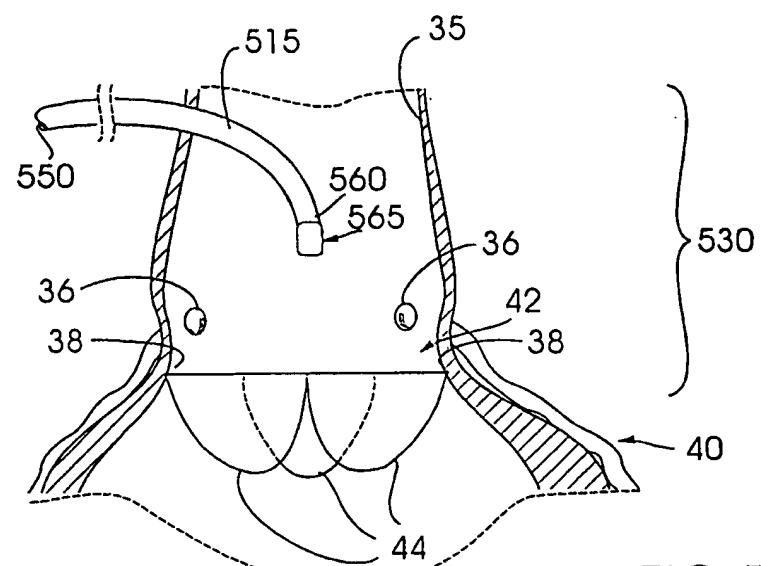


FIG 5

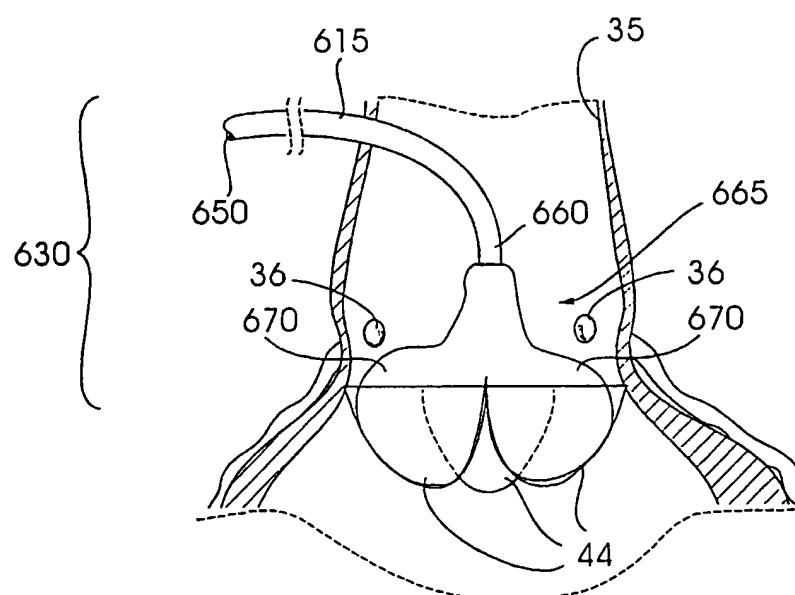


FIG 6

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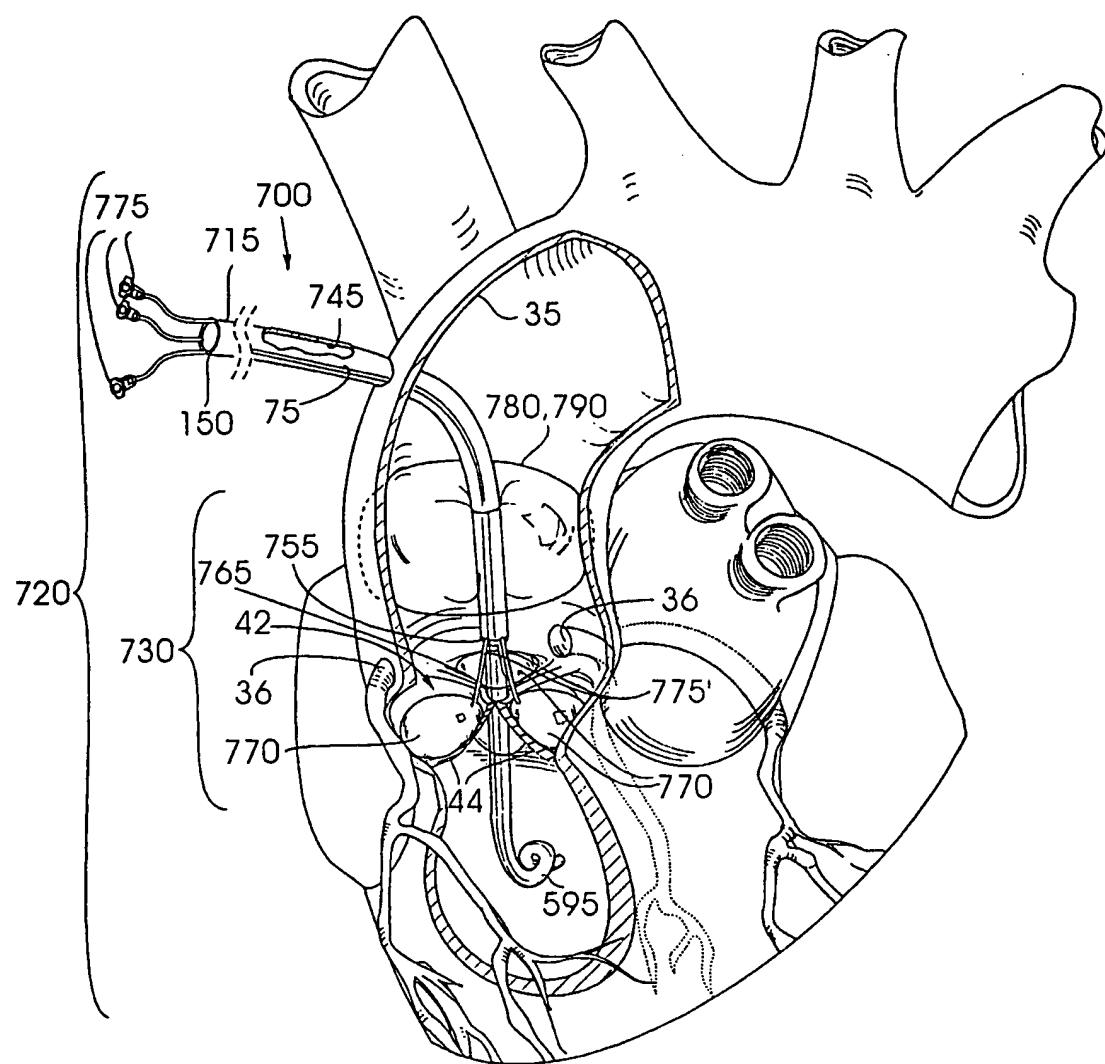
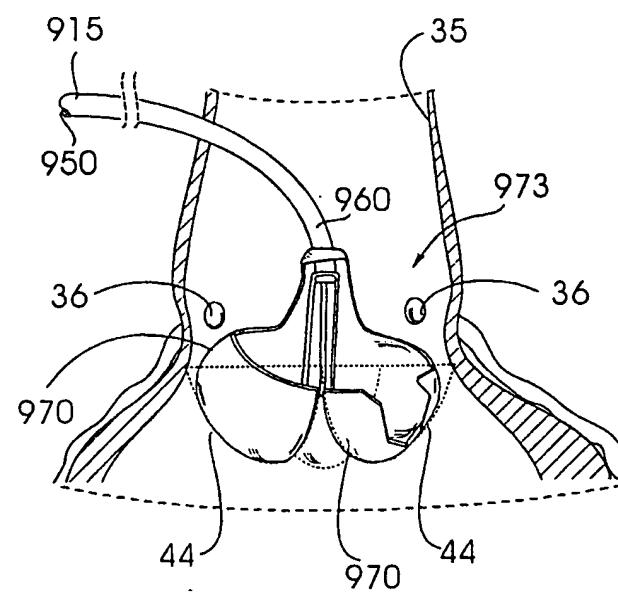
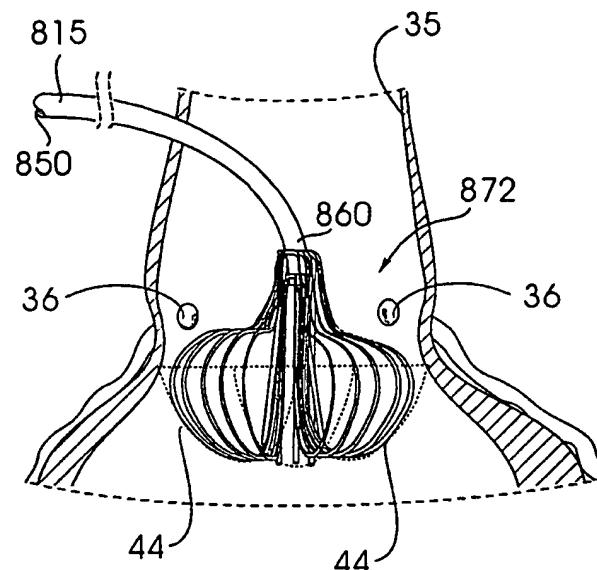


FIG 7

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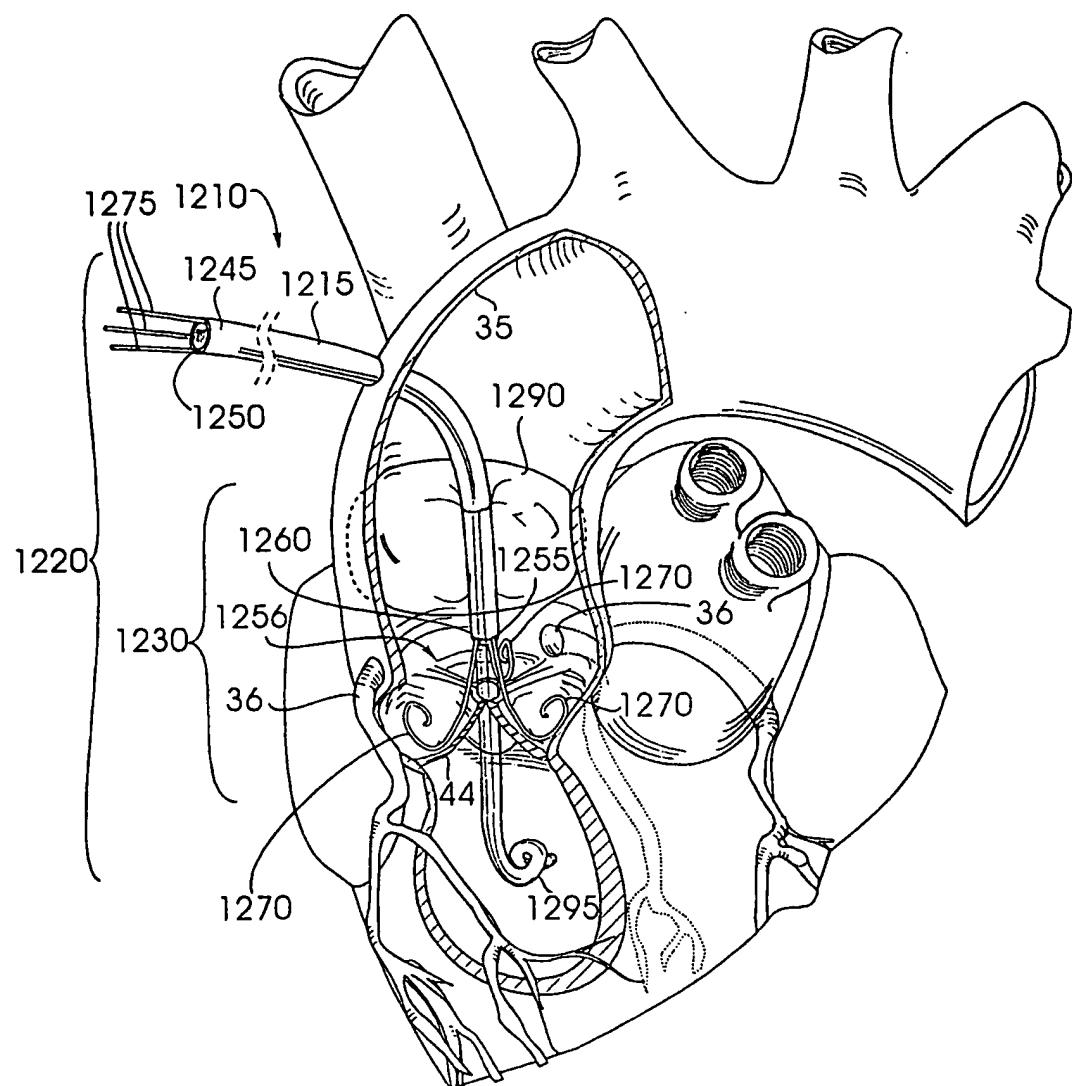
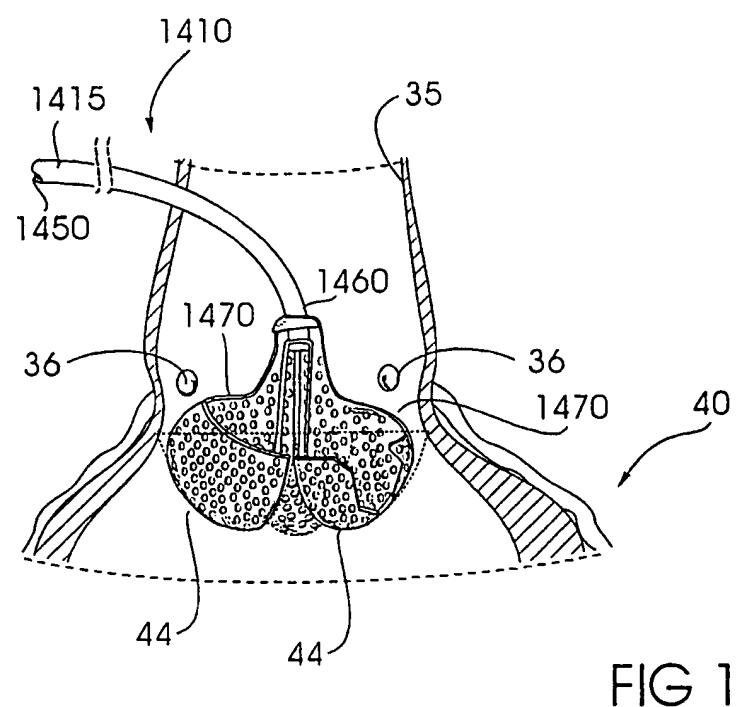
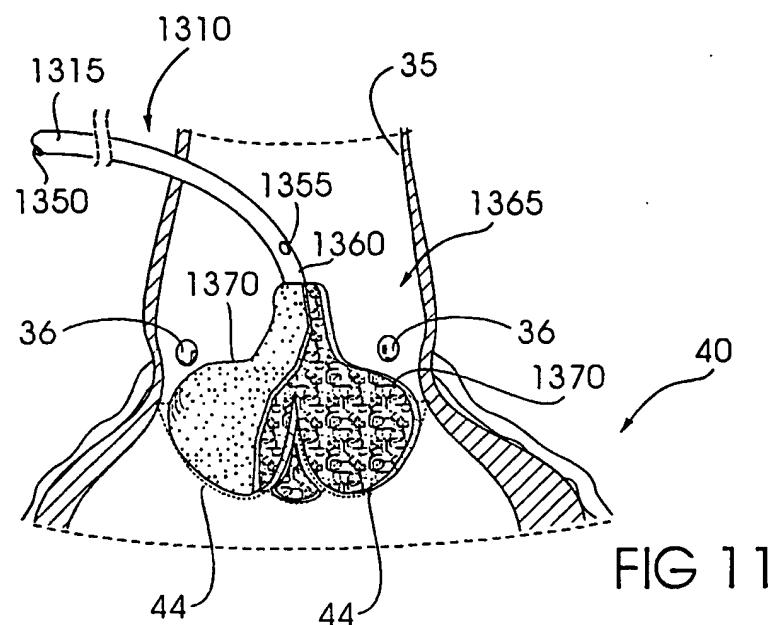
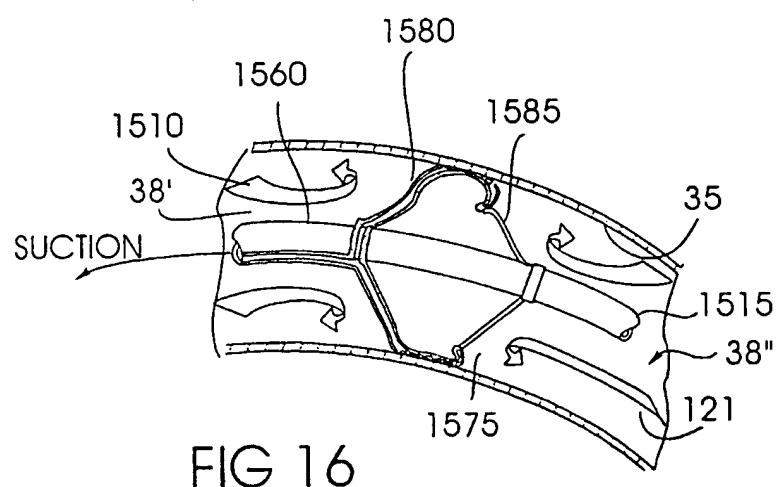
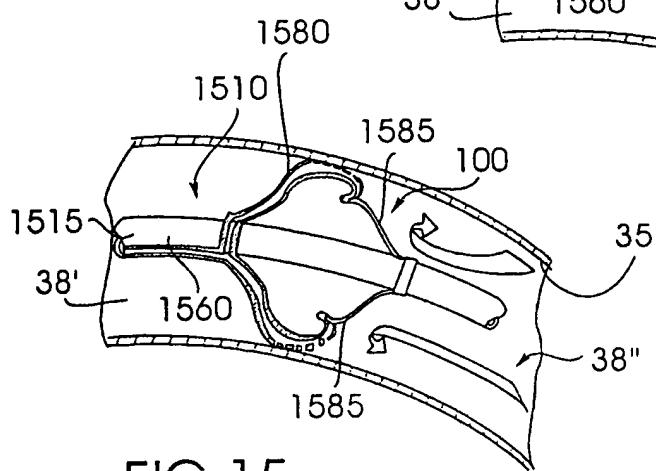
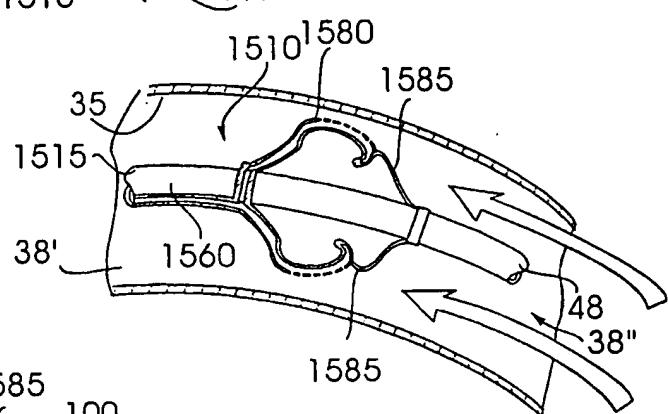
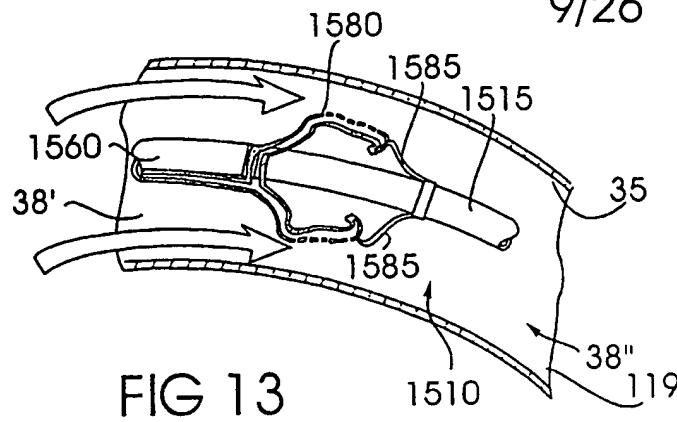


FIG 10

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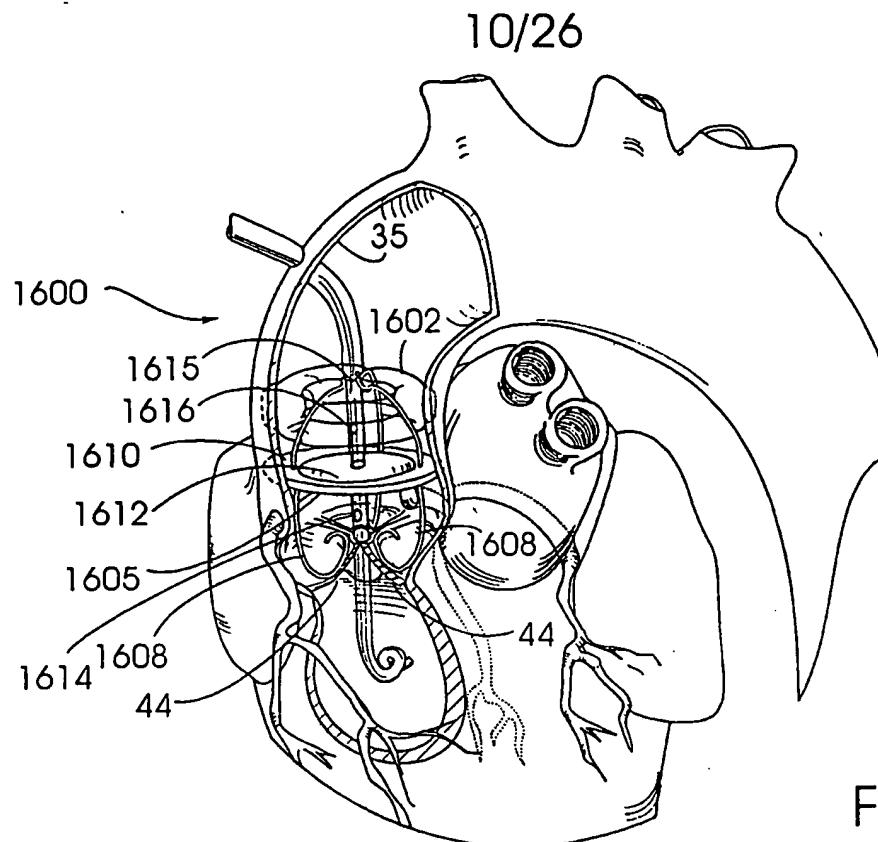


FIG 17

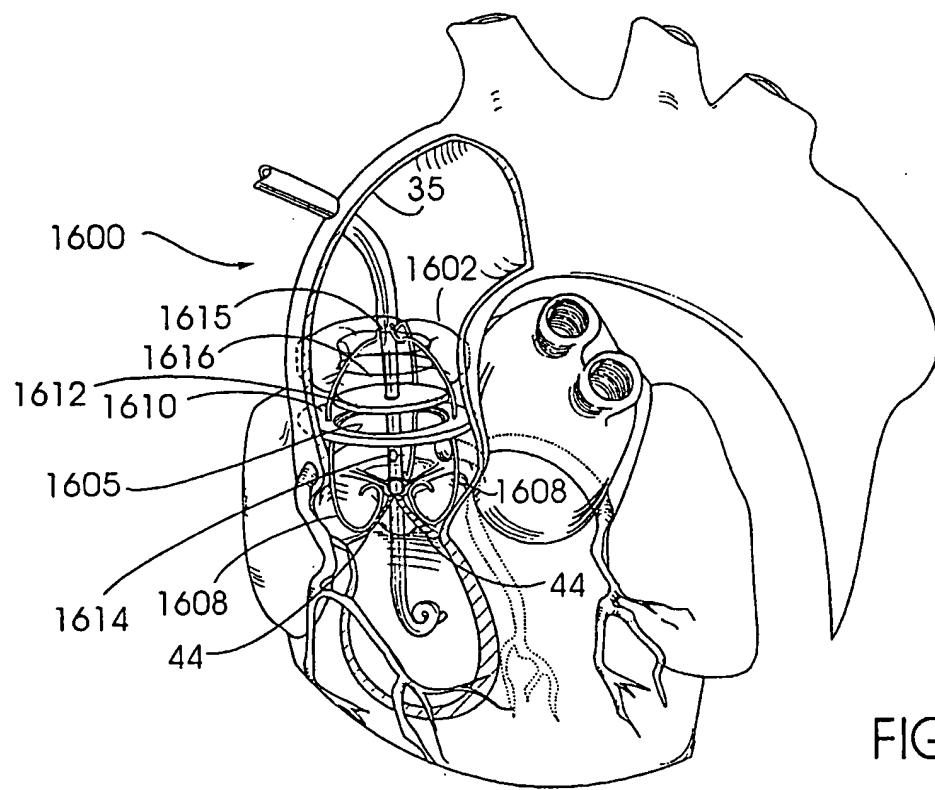


FIG 18

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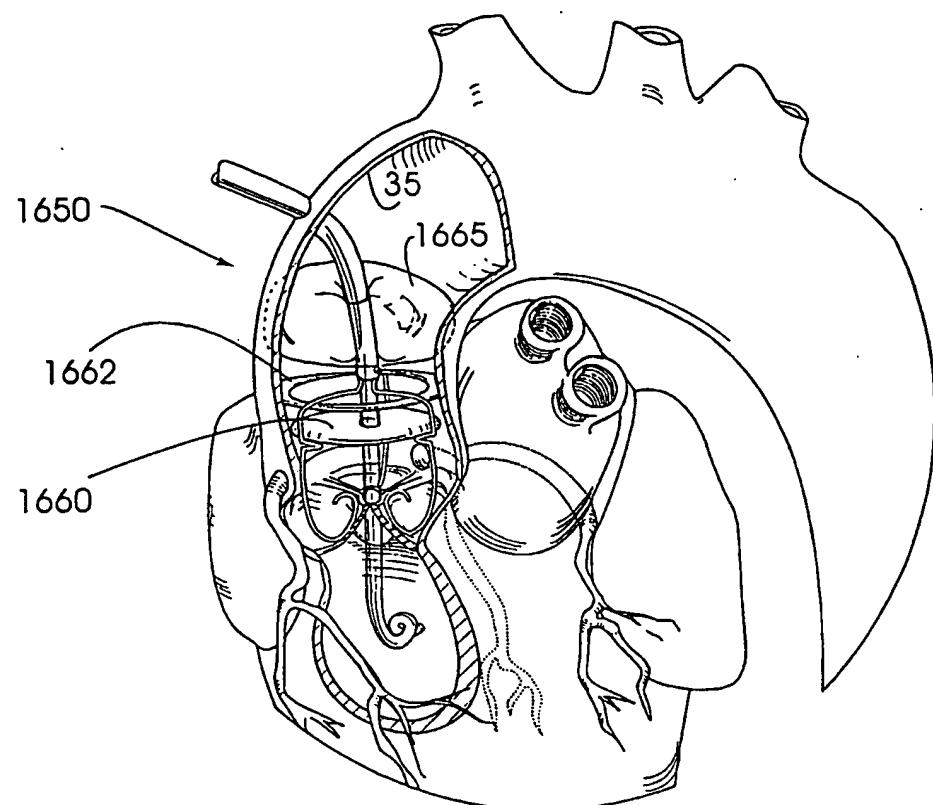


FIG 19

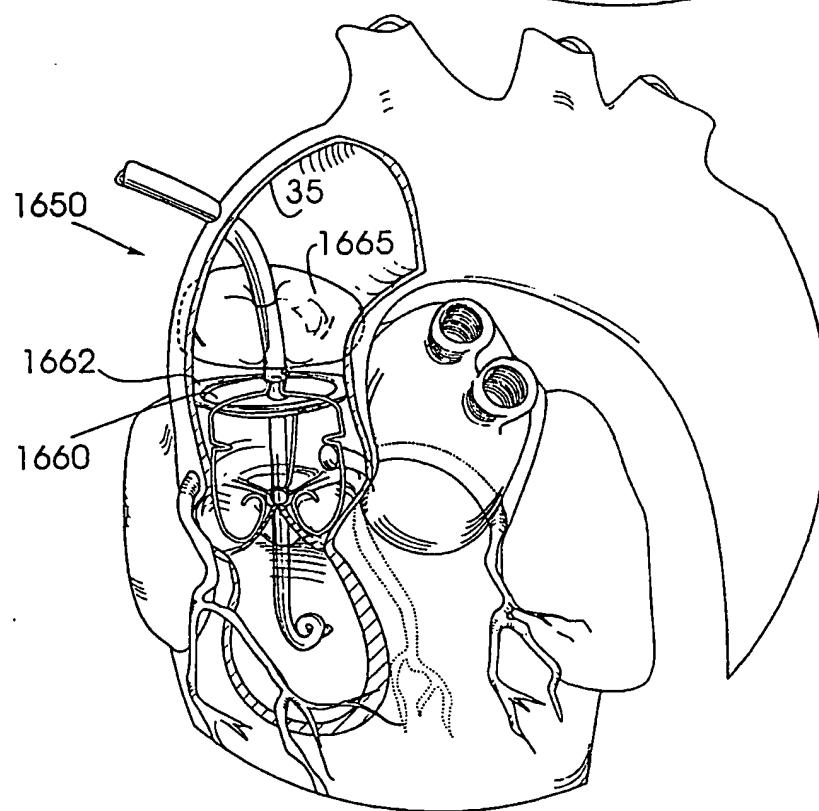


FIG 20

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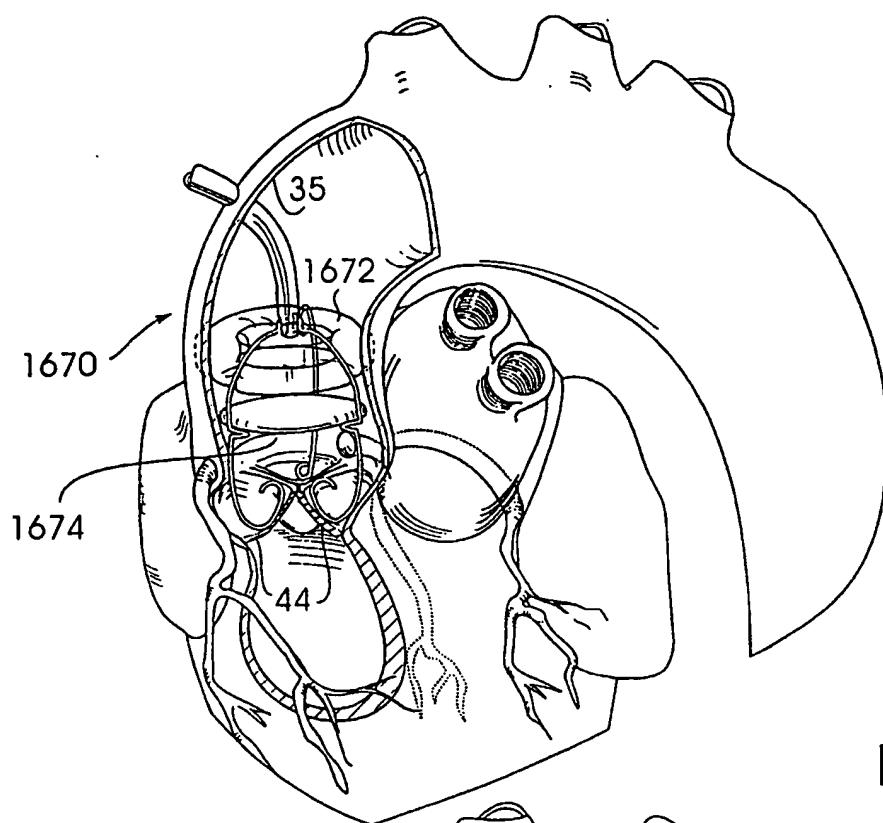


FIG 21

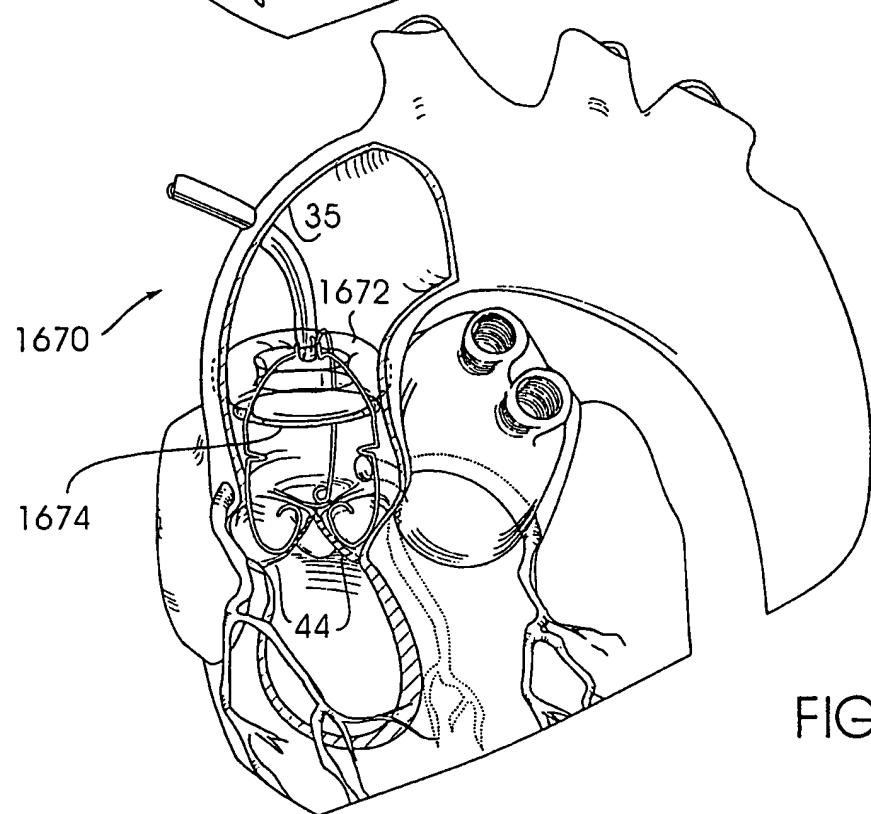


FIG 22

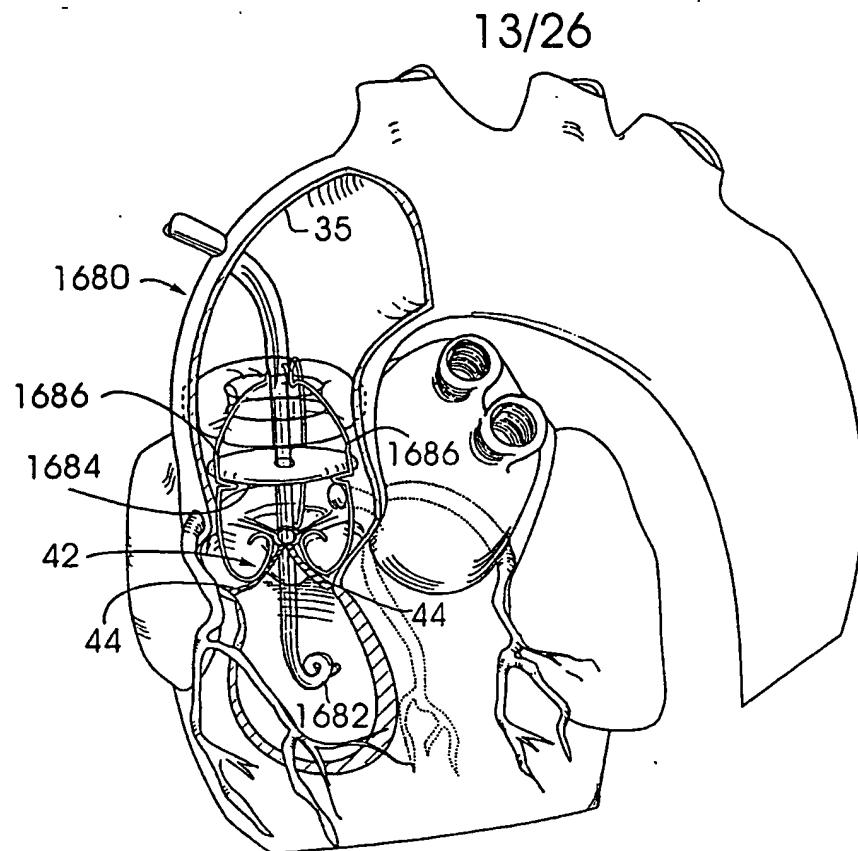


FIG 23

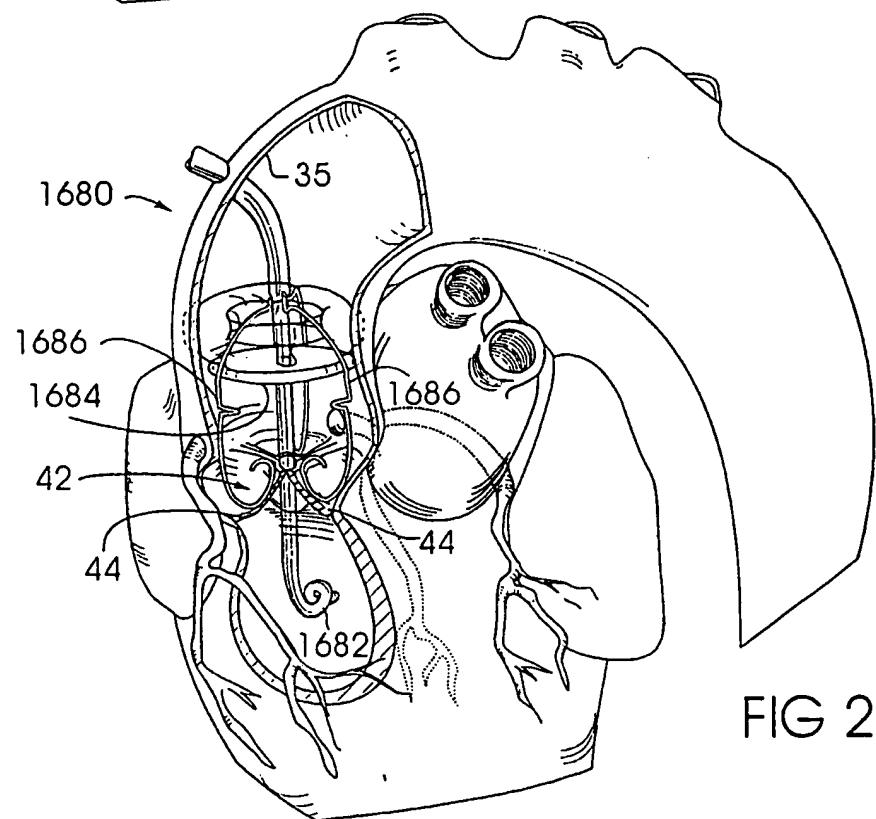
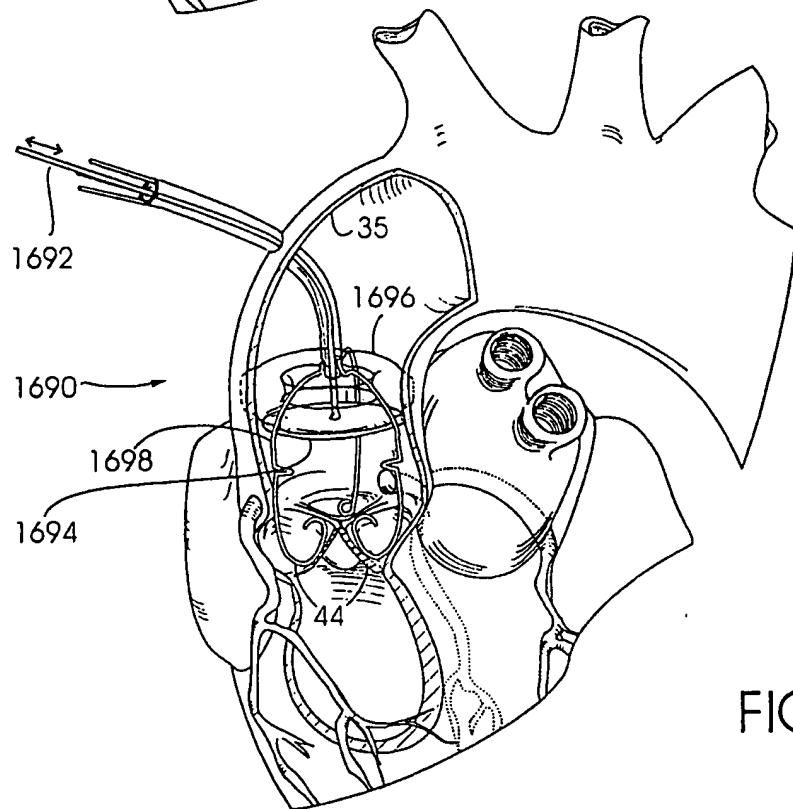
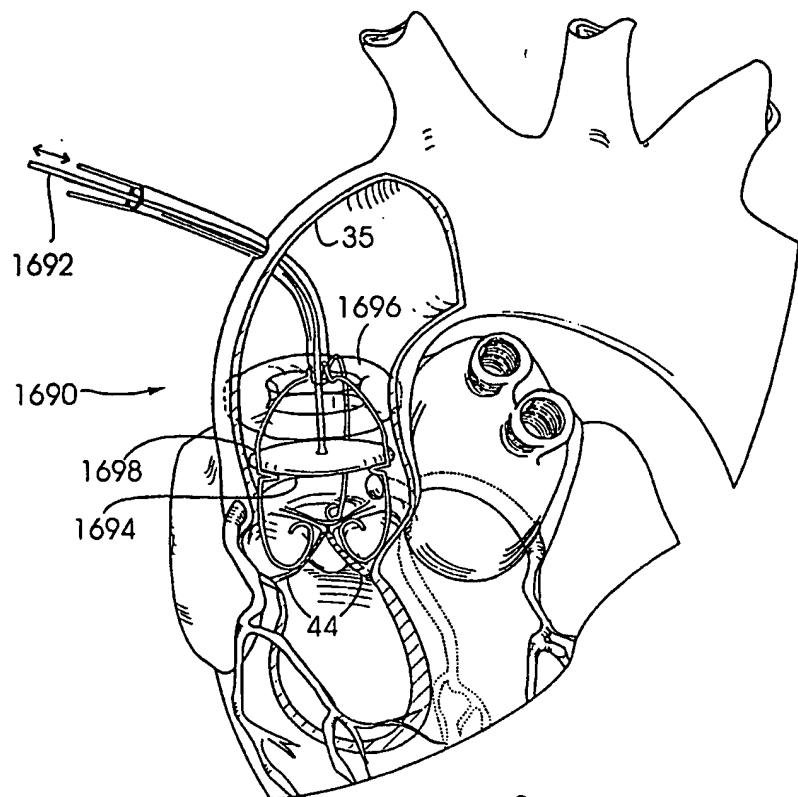


FIG 24

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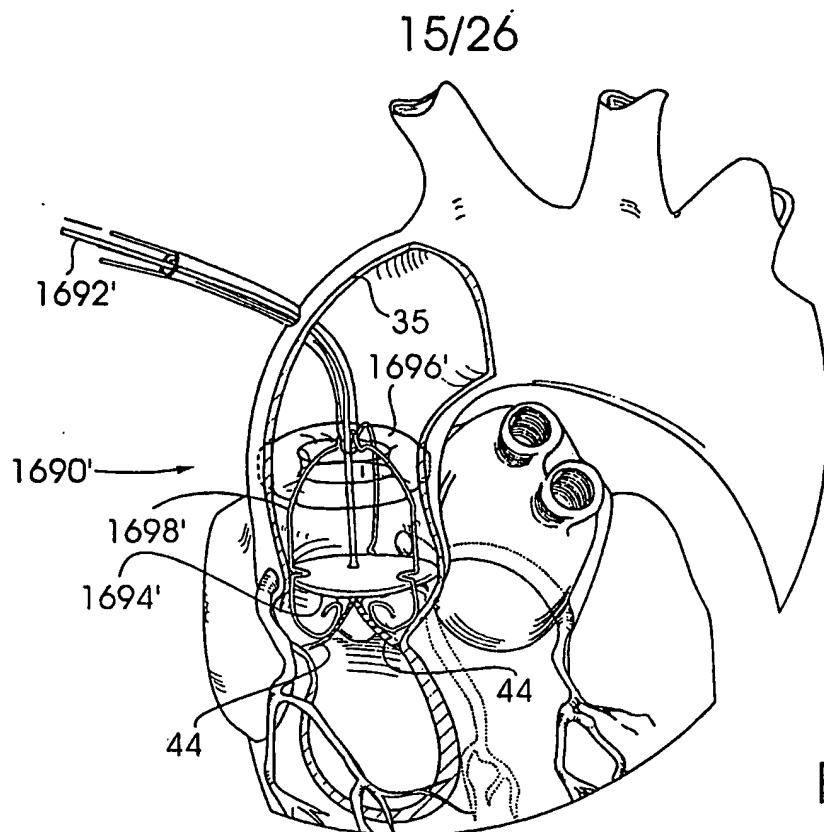


FIG 27

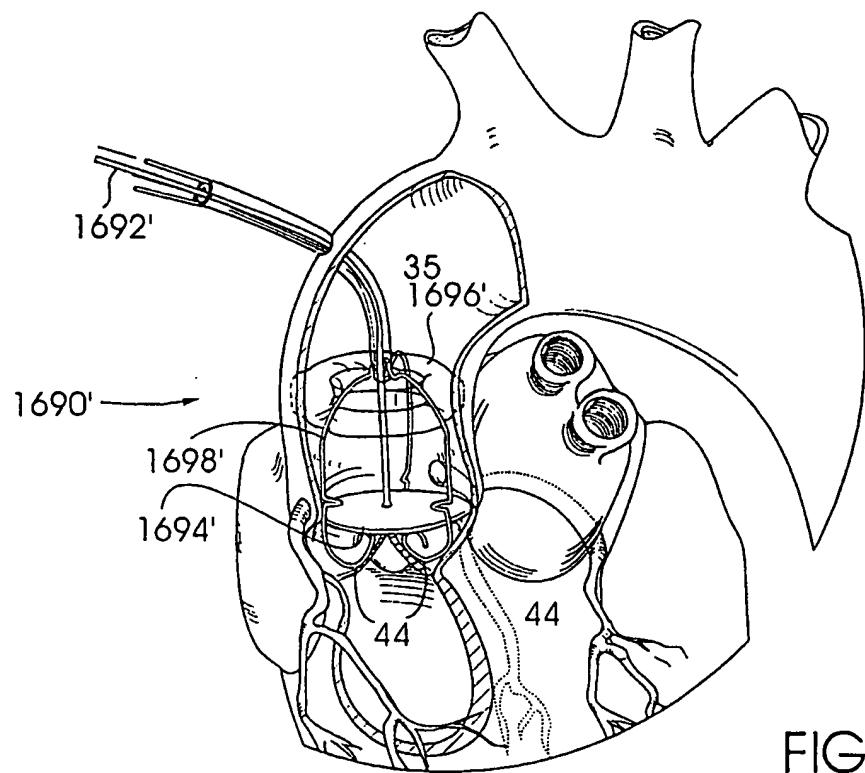


FIG 28

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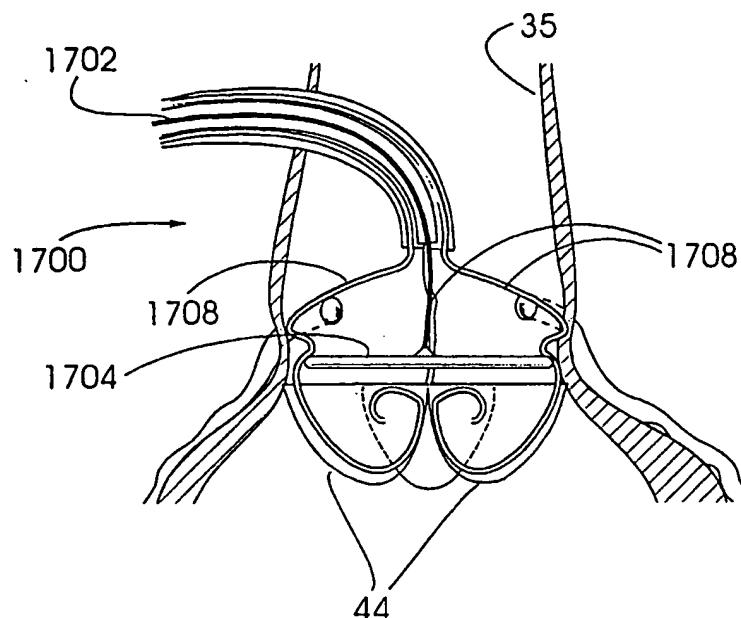


FIG 29

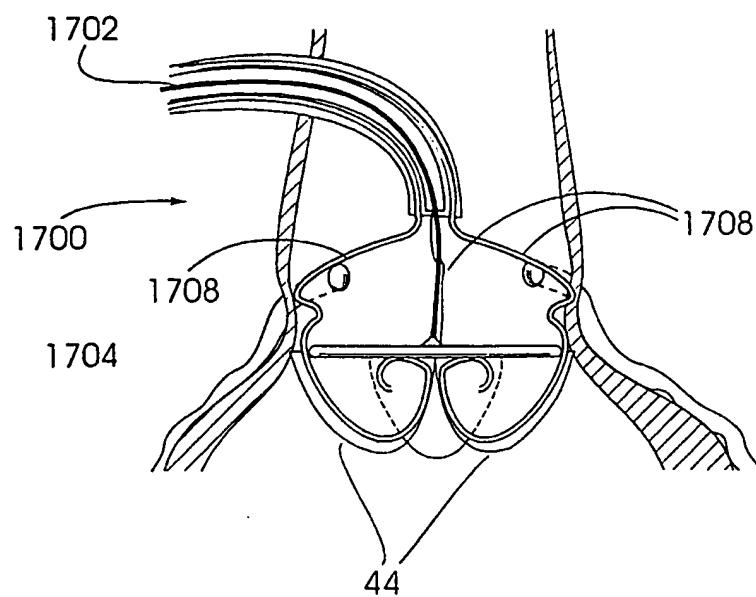


FIG 30

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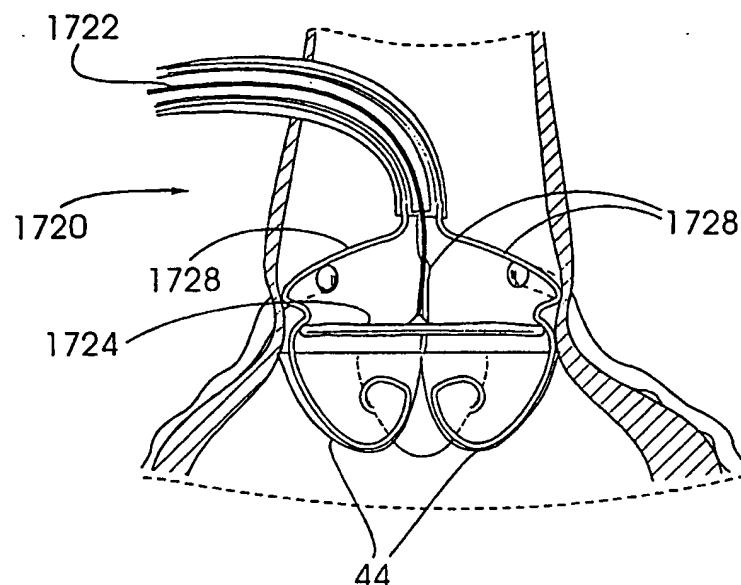


FIG 31

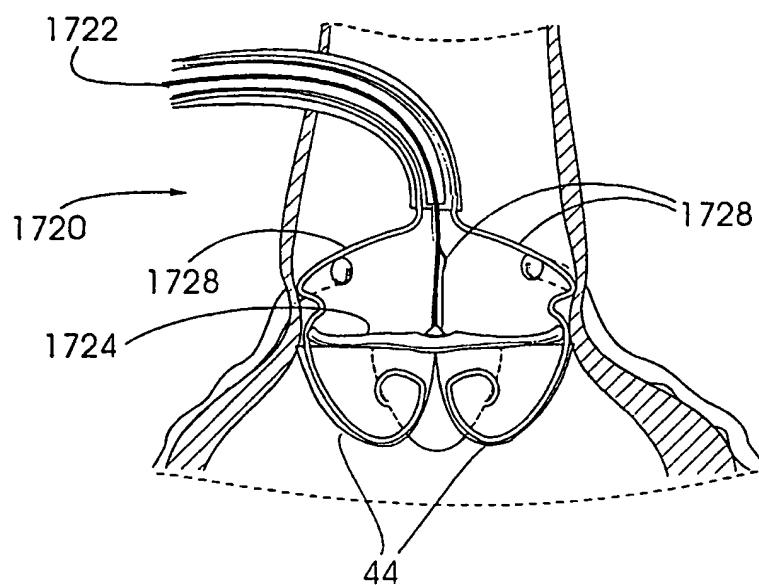


FIG 32

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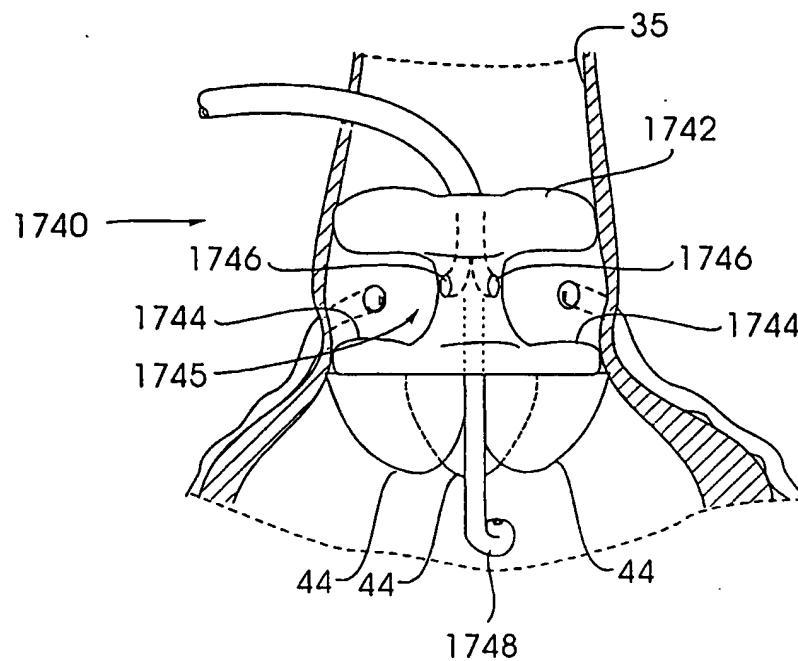


FIG 33

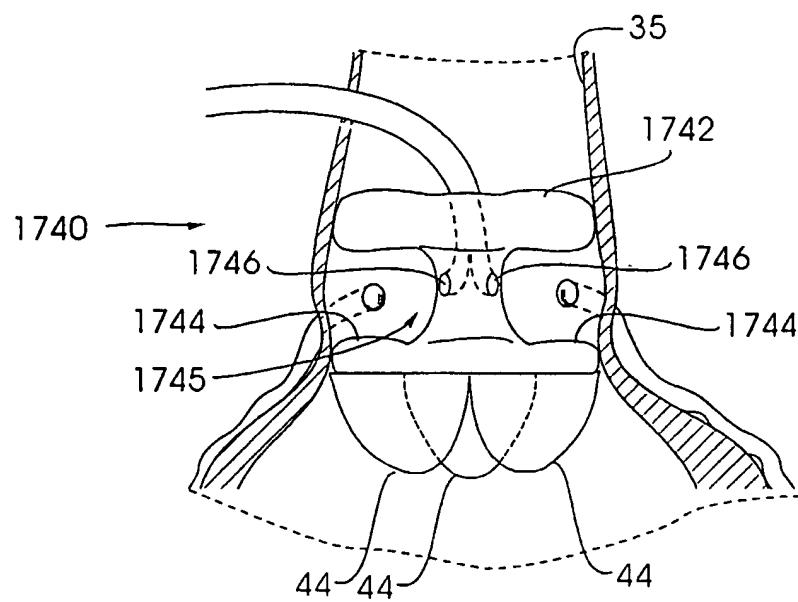


FIG 34

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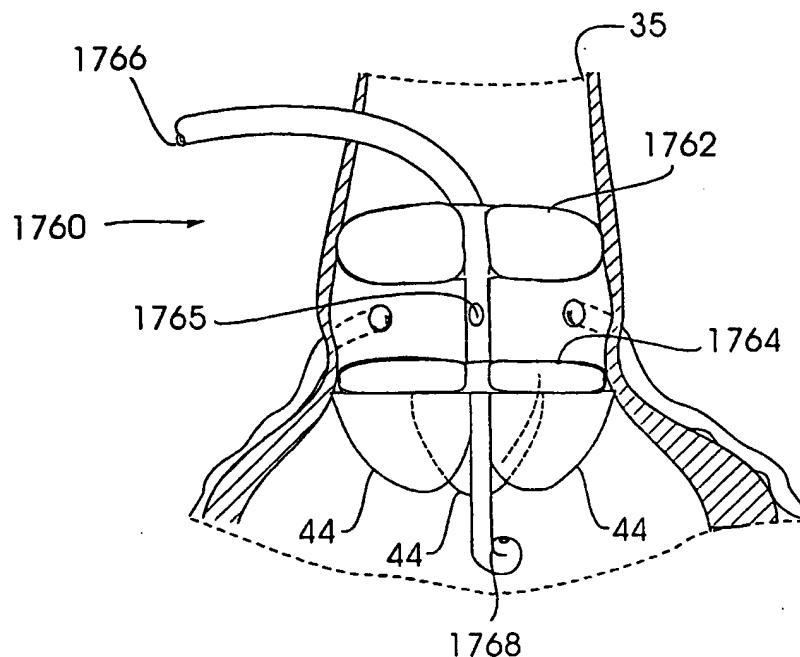


FIG 35

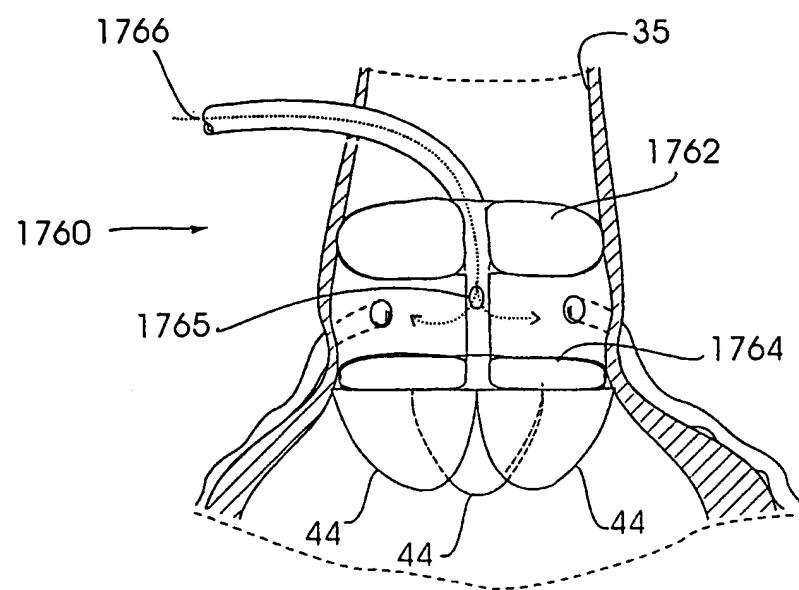


FIG 36

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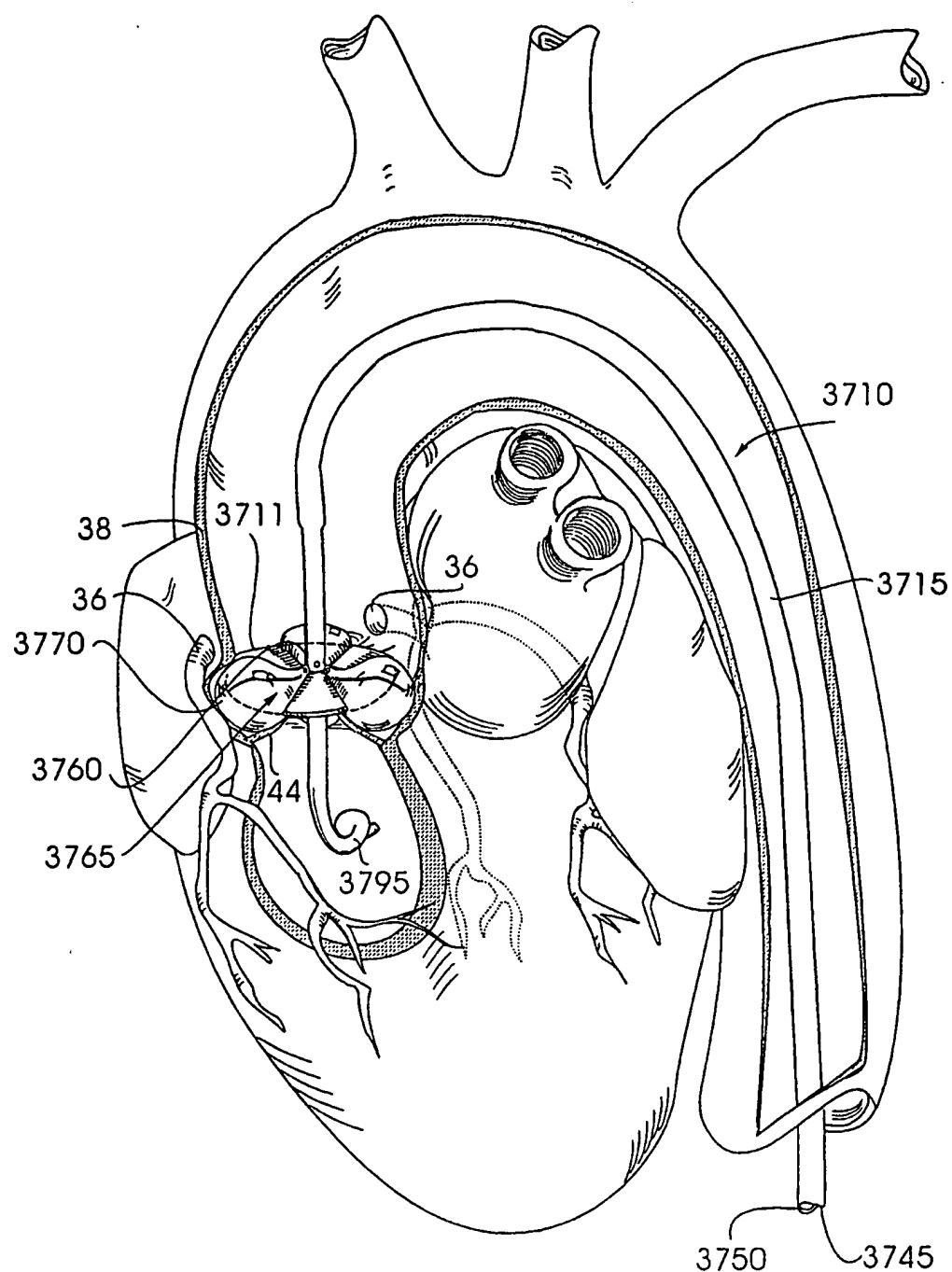


FIG 37

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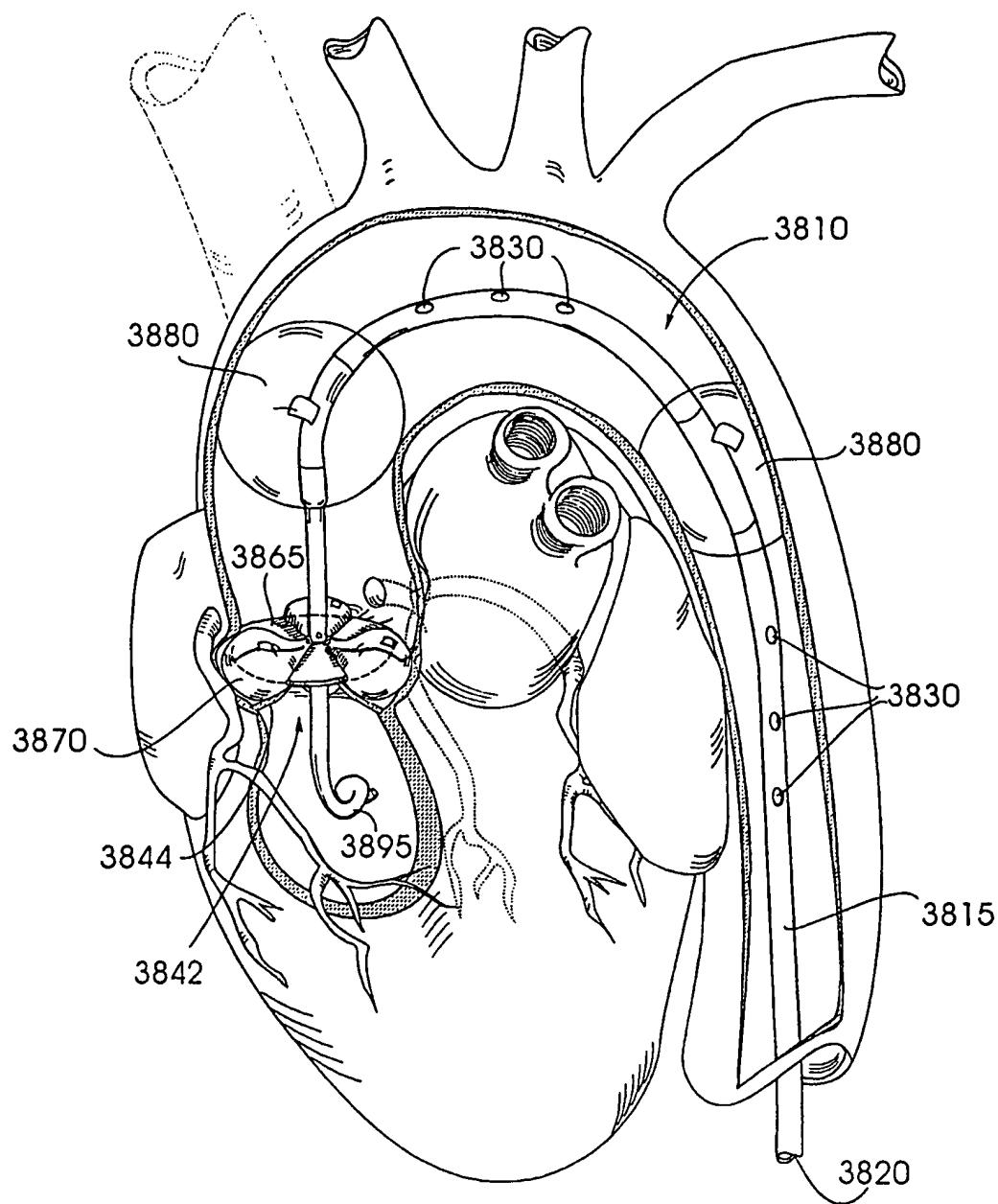


FIG 38

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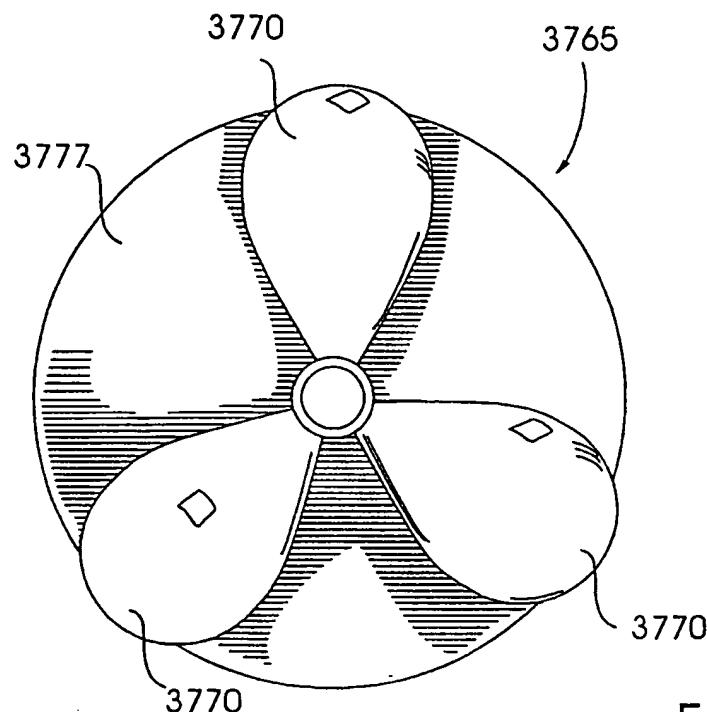


FIG 39

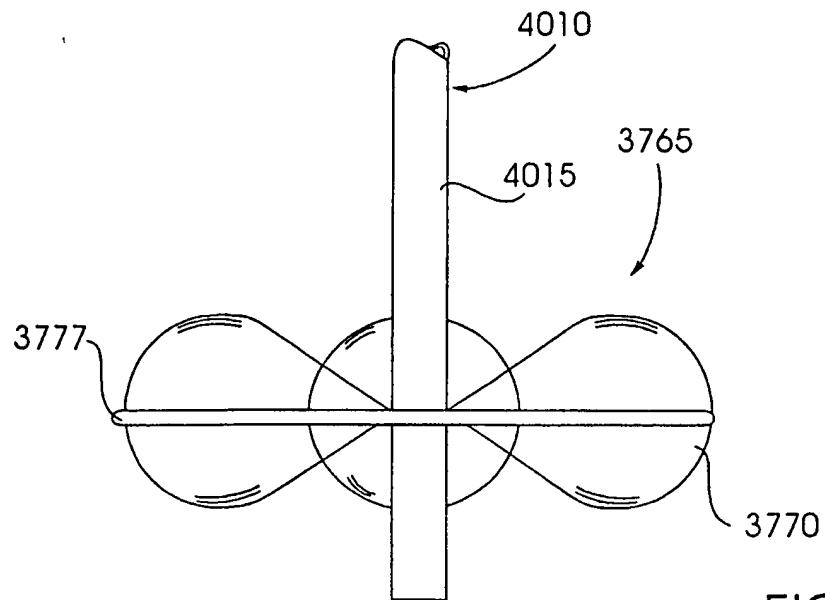


FIG 40

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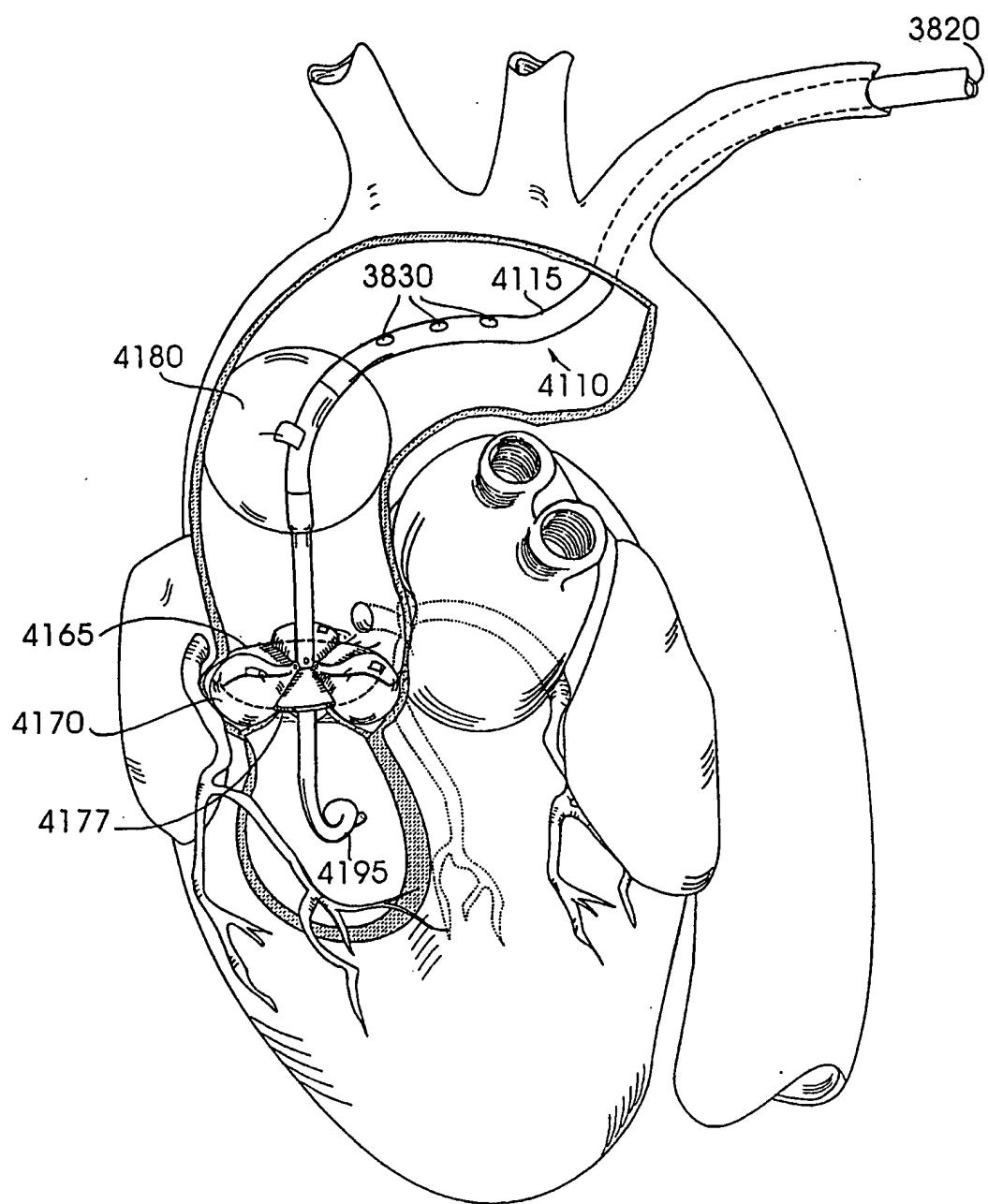


FIG 41

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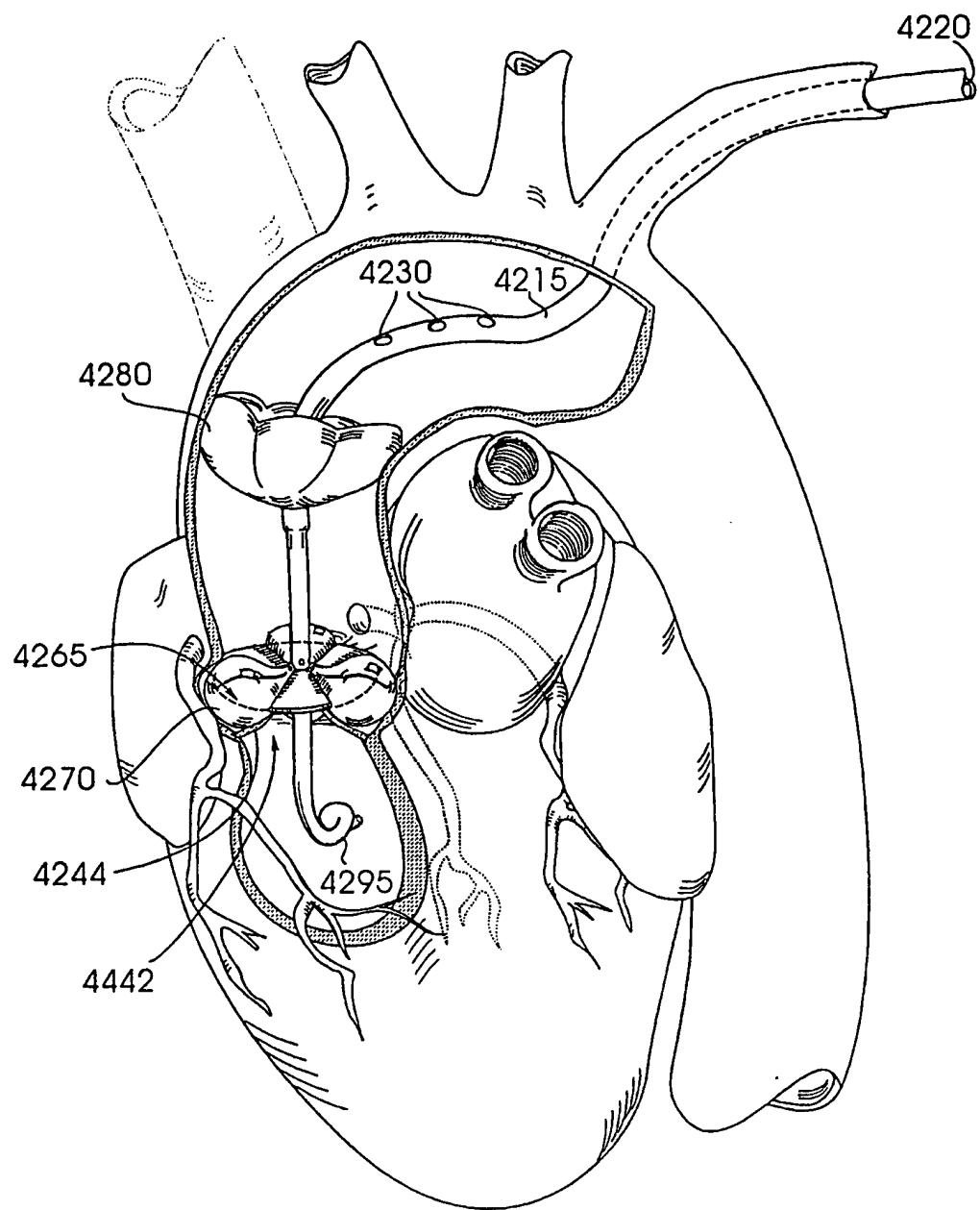


FIG 42

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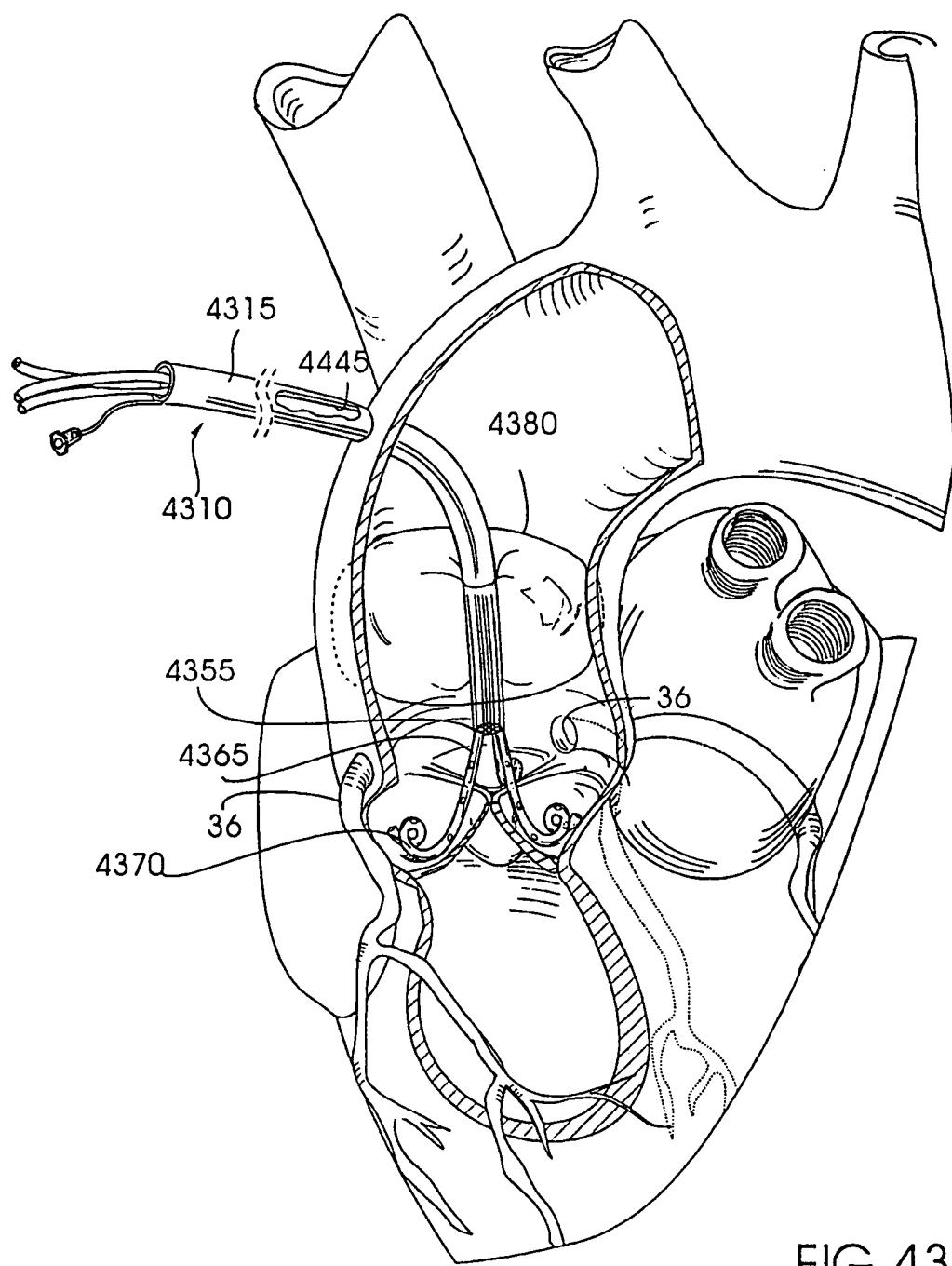


FIG 43

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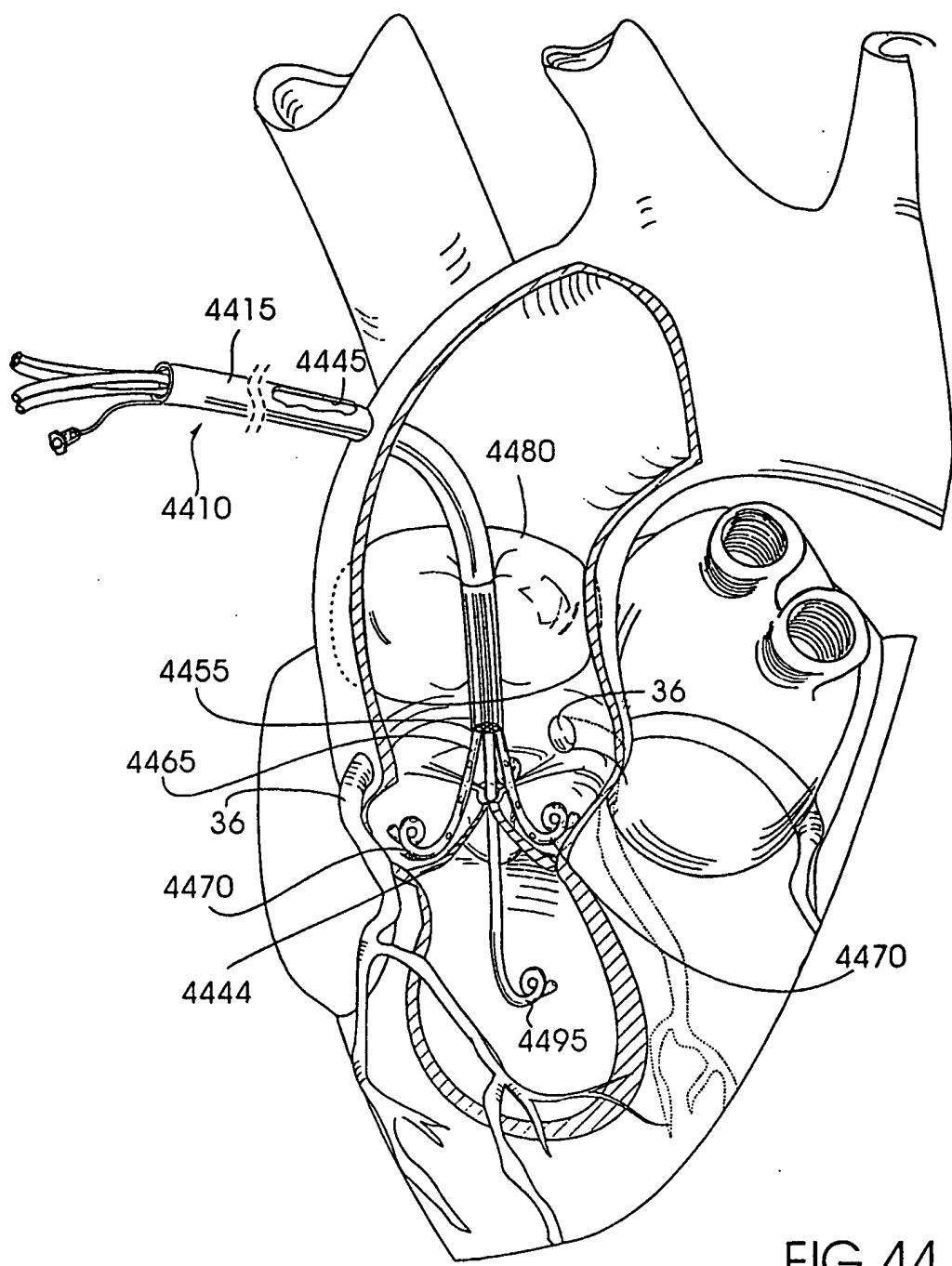


FIG 44

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/20225

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/10 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 21462 A (HEARTPORT) 19 June 1997 see page 60, line 8 - page 61, column 15; figure 29 --- US 5 167 628 A (BOYLES) 1 December 1992 see abstract; figure 2 --- WO 92 17118 A (SHTURMAN) 15 October 1992 see page 20, paragraph 3 - page 21, paragraph 2; figures 1,25 --- -/-	1,4,5,7, 15,16, 20, 48-51, 53,58 1,48 1,25,48, 59
A		

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

*** Special categories of cited documents :**

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search

26 January 1999

Date of mailing of the International search report

02/02/1999

Name and mailing address of the ISA

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Authorized officer

Moers, R

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/20225

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 061 240 A (CHERIAN) 29 October 1991 see abstract; figure 3 ---	1, 25, 48, 59
A	NL 8 303 510 A (KIST) 1 May 1985 see claims 1,6; figures 2,4 ---	3, 27, 52, 59
A	FR 2 529 083 A (FARCOT) 30 December 1983 see page 5, line 12 – line 20; figure 4 ---	9, 31, 54, 62
A	WO 93 01768 A (STEVENS) 4 February 1993 see page 13, line 1 – line 16; figures 7-10 -----	1, 25, 48, 59

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 98/20225

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 65-70
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/20225

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9721462 A	19-06-1997	US 5795325 A		18-08-1998
		AU 1296197 A		03-07-1997
US 5167628 A	01-12-1992	NONE		
WO 9217118 A	15-10-1992	US 5295958 A		22-03-1994
		AU 652902 B		08-09-1994
		AU 1677392 A		02-11-1992
		CA 2107231 A		05-10-1992
		EP 0578731 A		19-01-1994
		JP 6505416 T		23-06-1994
		US 5443446 A		22-08-1995
US 5061240 A	29-10-1991	NONE		
NL 8303510 A	01-05-1985	NONE		
FR 2529083 A	30-12-1983	FR 2502499 A		01-10-1982
		US 4459977 A		17-07-1984
WO 9301768 A	04-02-1993	US 5370685 A		06-12-1994
		AU 668690 B		16-05-1996
		AU 2412792 A		23-02-1993
		CA 2113476 A		04-02-1993
		EP 0597967 A		25-05-1994
		JP 6511167 T		15-12-1994
		US 5545214 A		13-08-1996
		US 5584803 A		17-12-1996
		US 5558644 A		24-09-1996
		US 5702368 A		30-12-1997
		US 5766151 A		16-06-1998
		US 5792094 A		11-08-1998
		US 5795325 A		18-08-1998
		US 5769812 A		23-06-1998
		US 5738652 A		14-04-1998
		US 5814016 A		29-09-1998